

US3492085 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:57:48

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US3492085

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 03:39:51

Generated On: 10 Jun 2021 07:57:48

[Participant ID](#)

US3492085

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

US3492085

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3492085

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	29
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	True

US3492085

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" 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

US3492085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3492085

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Were any significant conditions reported?

Yes ☒

No ☐

US3492085

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	SEASONAL ALLERGIES
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)	_____

US3492085

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	ASTHMA - MILD, INTERMITTENT
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492085

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492085

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	CELIAC DISEASE
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492085

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492085

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3492085

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	HISTORY OF MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2009
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3492085

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492085

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3492085

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3492085

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:05
Height (<i>xxx.x</i>)	161.5 cm
Weight (<i>xxx.x</i>)	73.8 kg
BMI (<i>xxx.x</i>)	28.29510 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	ND - Not Done
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)	

US3492085

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3492085

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Date of assessment (dd MMM yyyy) 08 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

US3492085

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	08 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3492085

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

US3492085

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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	False
Specify	

US3492085

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 112120

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Height	ND - Not Done
Weight	ND - Not Done

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:05
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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)	08 SEP 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:18
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 11:11 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 11:11

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

US3492085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

08 SEP 2020 10:20

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	08 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3492085

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 11:36

PC Open Date & Time

08 SEP 2020 11:31

PC Close Date & Time

08 SEP 2020 14:01

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 08 SEP 2020 14:56

PC Close Date & Time 09 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:08

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 19:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

98.3 °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

13 SEP 2020 19:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

97.8 °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

14 SEP 2020 19:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 12:12

PC Open Date & Time

08 SEP 2020 11:31

PC Close Date & Time

08 SEP 2020 14:01

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

08 SEP 2020 14:56

PC Close Date & Time

09 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

09 SEP 2020 19:07

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

10 SEP 2020 20:09

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

11 SEP 2020 19:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

12 SEP 2020 19:03

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

13 SEP 2020 19:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

14 SEP 2020 19:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:38
PC Open Date & Time	08 SEP 2020 11:31
PC Close Date & Time	08 SEP 2020 14:01

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 14:56

PC Close Date & Time

09 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 ☒

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:08
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 ☒

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

58 of 3295

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

60 of 3295

EAB) (1725)

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:03
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

62 of 3295

EAB) (1725)

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

64 of 3295

EAB) (1725)

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:07
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3492085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

29-09-2020 @ 12:18 LEFT A
MESSAGE

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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)	05 OCT 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 08:40
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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)	05 OCT 2020
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 10:36
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 05 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

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) 5 OCT 2020

What was the treatment time? (00:00-23:59) 10:01 (24 HR)

Treatment Date and Time (derived) 5 OCT 2020 10:01

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

What was the frequency of the study treatment dosing? ONCE

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

US3492085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 OCT 2020

Collection time (00:00-23:59)

09:25 (24 HR)

Collection date and time (derived)

05 OCT 2020 09:25

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Collection date (dd MMM yyyy)			05 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:39	05 OCT 2020 09:39
Nasopharyngeal Swab 2	No		

US3492085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 05 OCT 2020 10:42

PC Open Date & Time 05 OCT 2020 10:21

PC Close Date & Time 05 OCT 2020 12:51

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 OCT 2020 13:46

PC Close Date & Time

06 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

97.8 °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 OCT 2020 16:04

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 23:50

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 22:59

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

09 OCT 2020 23:14

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 23:26

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 22:07

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 10:43

PC Open Date & Time

05 OCT 2020 10:21

PC Close Date & Time

05 OCT 2020 12:51

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

05 OCT 2020 13:46

PC Close Date & Time

06 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

06 OCT 2020 16:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

07 OCT 2020 23:50

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

08 OCT 2020 23:00

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

09 OCT 2020 23:13

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

10 OCT 2020 23:26

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

11 OCT 2020 22:08

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 10:43
PC Open Date & Time	05 OCT 2020 10:21
PC Close Date & Time	05 OCT 2020 12:51

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 13:46

PC Close Date & Time

06 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 ☒

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 16:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

103 of 3295

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 23:51
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

105 of 3295

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 23:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 ☒

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 23:13
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

109 of 3295

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 23:27
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 ☒

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 OCT 2020 22:40

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 9

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 OCT 2020 19:49

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 12 OCT 2020 22:40

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3492085

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

PC Time stamp 12 OCT 2020 22:40

US3492085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	12 OCT 2020 22:40
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3492085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:42:19

Generated On: 10 Jun 2021 07:57:48

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:42:19

Generated On: 10 Jun 2021 07:57:48

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) _____

US3492085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:42:19

Generated On: 10 Jun 2021 07:57:48

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.

US3492085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:42:19

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:53

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 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	09 NOV 2020 16:50:28
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

16 NOV 2020 00:19:20

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 09:59:25
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 NOV 2020 11:23:29
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:06:19

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 16:09:22
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 11:25:52

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

28 DEC 2020 12:18:56

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 07:11:08

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

17 JAN 2021 17:53:18

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

23 JAN 2021 07:19:47

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

29 JAN 2021 20:16:16

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

08 FEB 2021 22:34:11

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 21:46:22

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

20 FEB 2021 00:03:16

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 10:54:10

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

14 MAR 2021 09:35:23

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 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	19 MAR 2021 08:47:31
Patient Cloud Open Date & Time	18 MAR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	150 of 3295

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

29 MAR 2021 10:37:55

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

01 APR 2021 07:21:25

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 16:00:28

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

23 APR 2021 19:31:37

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 MAY 2021 05:16:11
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

Patient Cloud Open Date & Time	23 SEP 2021 00:01
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Patient Cloud Close Date & Time	27 SEP 2021 23:59
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US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 <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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3492085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:57:48

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		02 MAR 2021 07:25:15

US3492085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:05 (24 HR)
Vital Signs Date and Time (derived)	20 MAR 2021 13:05
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 MAR 2021

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

US3492085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 MAR 2021
Collection time (00:00-23:59)	13:08 (24 HR)
Collection date and time (derived)	20 MAR 2021 13:08

US3492085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

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

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Date of Contact	2 NOV 2020
Time of Contact	10:00
Date and Time of Contact (derived)	2 NOV 2020 10:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Date of Visit 2 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 2 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Date of Contact	19 MAR 2021
Time of Contact	09:42
Date and Time of Contact (derived)	19 MAR 2021 09:42
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	14 MAR 2021	
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"/>

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EAB) (1725)

342 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	15 MAR 2021	
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"/>

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EAB) (1725)

346 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	16 MAR 2021	
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)

350 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	17 MAR 2021
------	-------------

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)

354 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	18 MAR 2021	
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)

358 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 type="checkbox"/>
Day 6	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	19 MAR 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 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)

362 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	20 MAR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
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)

366 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	21 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98 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 type="radio"/>
	Mild	<input checked="" 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)

370 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	22 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 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)

374 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	23 MAR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 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)

378 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	24 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 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)

382 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☐
Moderate ☐
Severe ☒
Not Done ☐

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 checked="" 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	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	25 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97 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)

386 of 3295

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 16:24:07

Generated On: 10 Jun 2021 07:57:48

Date of Visit	19 MAR 2021
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	19 MAR 2021
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

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
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)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 16:24:07

Generated On: 10 Jun 2021 07:57:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 MAR 2021
Day 5	Yes	23 MAR 2021
Day 7	Yes	25 MAR 2021
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3492085

Folder: Illness Visit (3)

Form: Saliva Collection

Generated On: 10 Jun 2021 07:57:48

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 10:27
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 NOV 2020

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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

Visit date (dd MMM yyyy)	19 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 11:50
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 MAR 2021

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

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.

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
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US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

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.

US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	<hr/>
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US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

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.

US3492085

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3492085

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	UNBLND_DECIDE

US3492085

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	1 FEB 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>)	1 FEB 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

US3492085

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Height	
Weight	
BMI (xxx.x)	

US3492085

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Height	
Weight	
BMI (xxx.x)	
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 FEB 2021
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 13:33
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Height	
Weight	
BMI (xxx.x)	
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 FEB 2021
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 14:46
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	EAR
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 FEB 2021

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

US3492085

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

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	1 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3492085

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

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) 1 FEB 2021

What was the treatment time? (00:00-23:59) 14:06 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 14:06

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

US3492085

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00-23:59)	13:12 (24 HR)
Collection date and time (derived)	1 FEB 2021 13:12

US3492085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	13:17
Collection Date and Time (derived)	1 FEB 2021 13:17

US3492085

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	OLD29

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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)	1 MAR 2021
Time of assessment (00:00-23:59)	12:54 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 12:54
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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)	1 MAR 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 14:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3492085

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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.

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	1 MAR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	13:18
Collection date and time (derived)	

US3492085

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

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) 1 MAR 2021

What was the treatment time? (00:00-23:59) 14:04 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 14:04

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

US3492085

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492085

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:05 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 13:05
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492085

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:24:08

Generated On: 10 Jun 2021 07:57:48

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.

US3492085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:24:07

Generated On: 10 Jun 2021 07:57:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	13:08 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:08

US3492085

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 03:39:51

Generated On: 10 Jun 2021 07:57:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

AEID

Adverse event

MUSCLE SORENESS FROM
EXERCISING-GENERALIZED

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 20 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 22 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003
EAB) (1725)

440 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

AEID

Adverse event

STREP THROAT

Was this a medically-attended AE?

Yes ☒
No ☐

Was this a Solicited Adverse Reaction?

Yes ☐
No ☒

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

Yes ☐
No ☒

Start date (dd MMM yyyy)

24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

25 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☒
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003
EAB) (1725)

442 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

<hr/>		WENT TO MIDWEST HEALTH CLINIC AND WAS PRESCRIBED AMOXICILLIN AND LIDOCAINE MOUTHWASH PARTICIPANT IS TAKING AUGMENTIN. PER SAFETY CALL DAYS 36 AND 43, RECEIVED 3 MORE COURSES OF ANTIBIOTICS, IS CURRENTLY COMPLETING AND IS FEELING BETTER, NOT COMPLETELY RESOLVED YET. EVENT COMPLETELY RESOLVED AS OF 25OCT2020.
<hr/>		
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)		
<hr/>		

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

AEID

Adverse event

FIBROMYALGIA FLARE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

445 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

AEID

Adverse event

DIARRHEA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

447 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DIARRHEA RESOLVED 24OCT2020.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

AEID	USA-US101-2020-MRNA-1273-P30 1000009
Adverse event	BENIGN RIGHT OVARIAN CYST
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)	26 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)	25 DEC 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	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)

449 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

PPT WENT TO EMERGENCY ROOM DUE TO RIGHT LOWER QUADRANT PAIN. SHE WAS DIAGNOSED WITH RIGHT OVARIAN CYST AFTER UNDERGOING AN ULTRASOUND. PPT WAS DISCHARGED TO HOME WITH A PRESCRIPTION FOR HYDROCODONE. PPT WILL FOLLOW UP WITH GYNECOLOGIST 09DEC2020. PPT IS RESTING AT HOME AND DENIES ANY OTHER SYMPTOMS. CYST WAS SURGICALLY REMOVED DECEMBER 10, PATHOLOGY WAS NEGATIVE, SEE PROCEDURE LOG

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)	

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

AEID	USA-US101-2020-MRNA-1273-P30 1000009
Adverse event	RIGHT LOWER QUADRANT PAIN
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)	26 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)	25 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	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)	452 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input 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	PARTICIPANT WENT TO THE ER FOR RIGHT LOWER QUADRANT PAIN AND WAS DIAGNOSED WITH AN OVARIAN CYST. SEE OVARIAN CYST AE AND PROCEDURES LOG FOR MORE INFORMATION
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

453 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

Admitted to ICU Derived (CSA Programming Field Only)

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

AEID

Adverse event

TONSILITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

455 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

AEID

Adverse event

MUSCLES ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

457 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

459 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

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

Yes ☒

No ☐

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

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

DAILY, AS NEEDED

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

PRODUCTION RELEASE (v12.003

462 of 3295

EAB) (1725)

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication ALBUTEROL MDI

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 2

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

EVERY 6 HOURS AS NEEDED

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

PRODUCTION RELEASE (v12.003

464 of 3295

EAB) (1725)

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

466 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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 2012	
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication TRUVADA

Prophylaxis Yes ☒
No ☐

Indication PREP

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

468 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication BIOTIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

470 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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 2015	
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

472 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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 2015	
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

474 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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 2015	
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

476 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication MIRENA IUD

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

478 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	UTERINE	
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED MUSCLE
SORENESS FROM EXERCISING

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)

480 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)	20 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication LIDOCAINE MOUTHWASH

Prophylaxis Yes ☐
No ☒

Indication PAIN RELIEF OF SORE THROAT

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)

482 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)		26 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 SEP 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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication STREP THROAT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

484 of 3295

EAB) (1725)

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)	26 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication AUGMENTIN

Prophylaxis Yes ☐
No ☒

Indication STREP THROAT

Dose per administration 875 / 125

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

486 of 3295

EAB) (1725)

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication STREP THROAT

Dose per administration 300

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)

488 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication STREP THROAT

Dose per administration 125

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

490 of 3295

EAB) (1725)

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

492 of 3295

EAB) (1725)

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BENIGN RIGHT OVARIAN CYST
PAIN

Dose per administration 800

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)

494 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 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"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication HYDROCODONE/ACETAMINOP
HEN 5/325

Prophylaxis Yes ☐
No ☒

Indication RIGHT OVARIAN CYST PAIN

Dose per administration 2

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)

496 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	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)	02 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication TONSILITIS

Dose per administration 300

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)

498 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication WALGREENS WOMEN'S
PROBIOTIC

Prophylaxis Yes ☒
No ☐

Indication PREVENT DIARRHEA FROM
ANTIBIOTIC

Dose per administration 5

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

If dose unit is Other, specify BILLION ACTIVE CULTURES
PER CAPSULE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

500 of 3295

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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 ☐

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 16:24:06

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Feb 2021 03:39:52

Generated On: 10 Jun 2021 07:57:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 DEC 2020	RIGHT OVARIAN CYST REMOVAL	Adverse Event	
02 DEC 2020	ULTRASOUND	Adverse Event	

US3492085

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:57:48

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

US3492085

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:57:48

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 ☐

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/DEC/2020 09:22
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

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	14/DEC/2020 20:24
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

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/JAN/2021 21:09
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

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/FEB/2021 15:21
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

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/FEB/2021 13:46
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

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/FEB/2021 14:07
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

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Mar 2021 01:42:18

Generated On: 10 Jun 2021 07:57:48

SAEID	USA-US101-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/MAR/2021 11:24
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

US3492085 (Prod: UIC Project WISH CRS)

US3492085

Form: Participant Creation

Generated On: 10 Jun 2021 07:57:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'US3492085'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:59:43

US3492085

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:58

US3492085

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:59:44

US3492085

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:15:58

US3492085

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered 'SCRN'	System	08 Sep 2020 20:15:58

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:59:45

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '29'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'YEARS'	System	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '30'	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:57:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:16:53

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Sep 2020'	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2020'	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:55:18
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:14:32
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:14:25
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:18:24
User entered 'Amendment 5 (5)'	(b) (4), (b) (6)	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 14:59:44

US3492085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'I'	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:07:42

US3492085

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:57:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:48

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:48
Data point term sent to Coder	System	08 Sep 2020 20:20:52
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2018'	System	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2018'	System	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:04

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 05:29:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 05:29:41
Data point term sent to Coder	System	08 Sep 2020 20:20:51
User entered 'ASTHMA - MILD, INTERMITTENT'	(b) (4), (b) (6)	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2014'	System	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2014'	System	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:22

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:48
Data point term sent to Coder	System	08 Sep 2020 20:20:52
User entered 'GERD'	(b) (4), (b) (6)	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2012'	System	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2012'	System	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:34

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Malabsorption conditions, HLT: Malabsorption syndromes, PT: Coeliac disease, LLT: Celiac disease - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:21:48
Data point term sent to Coder	System	08 Sep 2020 20:20:52
User entered 'CELIAC DISEASE'	(b) (4), (b) (6)	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2013'	System	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2013'	System	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:20:49

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
Data point term sent to Coder	System	08 Sep 2020 20:21:55
User entered 'ECZEMA'	(b) (4), (b) (6)	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2019'	System	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2019'	System	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:21:05

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
Data point term sent to Coder	System	08 Sep 2020 20:21:56
User entered 'FIBROMYALGIA'	(b) (4), (b) (6)	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2008'	System	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2008'	System	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:21:23

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:51
Data point term sent to Coder	System	08 Sep 2020 20:21:59
User entered 'HISTORY OF MIGRAINES'	(b) (4), (b) (6)	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2009'	System	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2009'	System	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2013'	System	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2013'	System	08 Sep 2020 20:21:42

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:22:52
Data point term sent to Coder	System	08 Sep 2020 20:21:57
User entered 'DEPRESSION'	(b) (4), (b) (6)	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2009'	System	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2009'	System	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:21:54

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:23:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:23:52
Data point term sent to Coder	System	08 Sep 2020 20:23:01
User entered 'ANXIETY'	(b) (4), (b) (6)	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2009'	System	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2009'	System	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	08 Sep 2020 20:22:05

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:24:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:24:06
Data point term sent to Coder	System	08 Sep 2020 20:23:01
User entered 'CHOLECYSTECTOMY'	(b) (4), (b) (6)	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2013'	System	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2013'	System	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'Jan 2013'	System	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '2013'	System	08 Sep 2020 20:22:42

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:05'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered '08 Sep 2020 10:05'	System	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '161.5' cm	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55
DataPoint set to visible.	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '73.8' kg	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55
DataPoint set to visible.	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered '28.29510'	System	08 Sep 2020 20:17:55
DataPoint set to visible.	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered 'kg/m2'	System	08 Sep 2020 20:17:55
DataPoint set to visible.	System	08 Sep 2020 15:08:09

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 14:01:13
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 20:23:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 20:23:00
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:37:15
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered 'bpm'	System	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered 'breaths/min'	System	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered 'mmHg'	System	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered 'mmHg'	System	08 Sep 2020 20:17:55

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06

US3492085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06

US3492085

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:20

US3492085

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:17:20

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:48

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:06

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:42:16
Query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:22:37
User opened query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 16:50:42
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:22:31
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:22:31
User entered '10:15'	(b) (4), (b) (6)	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User entered empty.	System	12 Oct 2020 15:22:31
User entered '08 Sep 2020 10:15'	System	08 Sep 2020 20:23:37

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:03:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:39:23

US3492085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:38:27

US3492085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:38:27

US3492085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:38:27

US3492085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'VISIT1'	System	08 Sep 2020 15:38:27

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:39:23

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '112120'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:39:23

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:39:23

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

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)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:24

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

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)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:24

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:24

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:24

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:45:24

US3492085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:48

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
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	30 Oct 2020 16:04:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:04:32
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 14:34:04
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:34:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:08:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:37:45

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:35:41
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:23:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:23:42
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:14:45
User entered '161.5' cm	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:23:42
User entered '73.8' kg	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:35:41
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:23:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:23:42
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:14:45
User entered '161.5' cm	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:23:42
User entered '73.8' kg	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:05'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '08 Sep 2020 10:05'	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'TYMPANIC'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '60'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'bpm'	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '20'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'breaths/min'	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '108'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '68'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:35:41
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:23:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:23:42
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:14:45
User entered '161.5' cm	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:23:42
User entered '73.8' kg	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 14:12:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 14:12:30
User entered '11:18' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:30
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:19:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '08 Sep 2020 11:18'	System	10 Sep 2020 14:12:30
User entered empty.	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 14:12:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 14:12:30
User entered '97.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:30
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:19:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	10 Sep 2020 14:12:47
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 14:12:47
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:47
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 14:12:30
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tympanic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:12:47
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 14:12:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 14:12:30
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:30
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:19:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'bpm'	System	10 Sep 2020 14:12:30
User entered empty.	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 14:12:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 14:12:30
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:30
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:19:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'breaths/min'	System	10 Sep 2020 14:12:30
User entered empty.	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 14:12:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 14:12:30
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:30
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:19:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	10 Sep 2020 14:12:30
User entered empty.	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 14:12:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 14:12:30
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:12:30
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:19:18
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	10 Sep 2020 14:12:30
User entered empty.	System	08 Sep 2020 20:19:18

US3492085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:28

US3492085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:19:28

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:42:23
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:22:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:22:05
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 16:50:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:22:05
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:22:05
User entered 'Urine (URINE)'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:22:05
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:42:26
Query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:22:16
User opened query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 16:50:06
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:22:05
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:22:05
User entered '10:15'	(b) (4), (b) (6)	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered empty.	System	12 Oct 2020 15:22:05
User entered '08 Sep 2020 10:15'	System	08 Sep 2020 20:24:04

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '11:11'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered '08 Sep 2020 11:11'	System	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'ONCE'	System	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 16:13:18

US3492085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:45

US3492085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:45

US3492085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:45

US3492085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered '08 Sep 2020 10:20'	System	10 Sep 2020 13:57:45

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:30'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered '08 Sep 2020 10:30'	System	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered empty.	System	10 Sep 2020 13:57:28

US3492085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 13:57:01

US3492085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	10 Sep 2020 13:57:01

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:31:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3dab6809-08a1-4648-9a73-62075afe01f7'	System	08 Sep 2020 16:36:19
User entered 'Yes (Y)'	System	08 Sep 2020 16:36:19

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:35:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3dab6809-08a1-4648-9a73-62075afe01f7'	System	08 Sep 2020 16:36:19
User entered '98.0'	System	08 Sep 2020 16:36:19

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:36:10', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3dab6809-08a1-4648-9a73-62075afe01f7'	System	08 Sep 2020 16:36:19
User entered 'No (N)'	System	08 Sep 2020 16:36:19

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:36:15', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3dab6809-08a1-4648-9a73-62075afe01f7'	System	08 Sep 2020 16:36:19
User entered '08 Sep 2020 11:36'	System	08 Sep 2020 16:36:19

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 11:31'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 14:01'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 14:56'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 2'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:05:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '060d7ff4-f9a8-4996-bd25-5c009d79f6c8'	System	10 Sep 2020 00:06:17
User entered 'Yes (Y)'	System	10 Sep 2020 00:06:17

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:05:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '060d7ff4-f9a8-4996-bd25-5c009d79f6c8'	System	10 Sep 2020 00:06:17
User entered '98.2'	System	10 Sep 2020 00:06:17

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:06:01', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '060d7ff4-f9a8-4996-bd25-5c009d79f6c8'	System	10 Sep 2020 00:06:17
User entered 'No (N)'	System	10 Sep 2020 00:06:17

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:06:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '060d7ff4-f9a8-4996-bd25-5c009d79f6c8'	System	10 Sep 2020 00:06:17
User entered '09 Sep 2020 19:06'	System	10 Sep 2020 00:06:17

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 3'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:08:06', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'bf8da868-682b-47e7-8fce-2dcd9b934ba1'	System	11 Sep 2020 01:08:47
User entered 'Yes (Y)'	System	11 Sep 2020 01:08:47

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:08:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'bf8da868-682b-47e7-8fce-2dcd9b934ba1'	System	11 Sep 2020 01:08:47
User entered '97.1'	System	11 Sep 2020 01:08:47

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:08:42', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'bf8da868-682b-47e7-8fce-2dcd9b934ba1'	System	11 Sep 2020 01:08:47
User entered 'No (N)'	System	11 Sep 2020 01:08:47

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:08:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'bf8da868-682b-47e7-8fce-2dcd9b934ba1'	System	11 Sep 2020 01:08:47
User entered '10 Sep 2020 20:08'	System	11 Sep 2020 01:08:47

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 4'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:11:38', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '8a588b9c-b66e-4f2c-bc74-ded303c94f3d'	System	12 Sep 2020 00:12:36
User entered 'Yes (Y)'	System	12 Sep 2020 00:12:36

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '8a588b9c-b66e-4f2c-bc74-ded303c94f3d'	System	12 Sep 2020 00:12:36
User entered '98.0'	System	12 Sep 2020 00:12:36

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '8a588b9c-b66e-4f2c-bc74-ded303c94f3d'	System	12 Sep 2020 00:12:36
User entered 'No (N)'	System	12 Sep 2020 00:12:36

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:31', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '8a588b9c-b66e-4f2c-bc74-ded303c94f3d'	System	12 Sep 2020 00:12:36
User entered '11 Sep 2020 19:12'	System	12 Sep 2020 00:12:36

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 5'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:01:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '45a2c24b-25fd-4b7f-841d-299688bdfbb5'	System	13 Sep 2020 00:02:45
User entered 'Yes (Y)'	System	13 Sep 2020 00:02:45

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:02:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '45a2c24b-25fd-4b7f-841d-299688bdfbb5'	System	13 Sep 2020 00:02:45
User entered '97.5'	System	13 Sep 2020 00:02:45

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:02:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '45a2c24b-25fd-4b7f-841d-299688bdfbb5'	System	13 Sep 2020 00:02:45
User entered 'No (N)'	System	13 Sep 2020 00:02:45

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:02:40', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '45a2c24b-25fd-4b7f-841d-299688bdfbb5'	System	13 Sep 2020 00:02:45
User entered '12 Sep 2020 19:02'	System	13 Sep 2020 00:02:45

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 6'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:01:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef480bbd-3ad0-4cb0-8382-c6e0336d2aff'	System	14 Sep 2020 00:02:30
User entered 'Yes (Y)'	System	14 Sep 2020 00:02:30

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:13', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef480bbd-3ad0-4cb0-8382-c6e0336d2aff'	System	14 Sep 2020 00:02:30
User entered '98.3'	System	14 Sep 2020 00:02:30

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef480bbd-3ad0-4cb0-8382-c6e0336d2aff'	System	14 Sep 2020 00:02:30
User entered 'No (N)'	System	14 Sep 2020 00:02:30

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:27', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef480bbd-3ad0-4cb0-8382-c6e0336d2aff'	System	14 Sep 2020 00:02:30
User entered '13 Sep 2020 19:02'	System	14 Sep 2020 00:02:30

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 7'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:05:37', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd9785ee4-aa74-456e-be44-27a9f5abb90a'	System	15 Sep 2020 00:06:04
User entered 'Yes (Y)'	System	15 Sep 2020 00:06:04

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:05:42', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd9785ee4-aa74-456e-be44-27a9f5abb90a'	System	15 Sep 2020 00:06:04
User entered '97.8'	System	15 Sep 2020 00:06:04

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:05:59', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd9785ee4-aa74-456e-be44-27a9f5abb90a'	System	15 Sep 2020 00:06:04
User entered 'No (N)'	System	15 Sep 2020 00:06:04

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:06:01', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd9785ee4-aa74-456e-be44-27a9f5abb90a'	System	15 Sep 2020 00:06:04
User entered '14 Sep 2020 19:06'	System	15 Sep 2020 00:06:04

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T12:09:33', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '901b9b1b-b38f-4e72-a375-3b90bf34d2db'	System	08 Sep 2020 17:12:19
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 17:12:19

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T12:09:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '901b9b1b-b38f-4e72-a375-3b90bf34d2db'	System	08 Sep 2020 17:12:19
User entered 'No (N)'	System	08 Sep 2020 17:12:19

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T12:09:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '901b9b1b-b38f-4e72-a375-3b90bf34d2db'	System	08 Sep 2020 17:12:19
User entered 'Yes (Y)'	System	08 Sep 2020 17:12:19

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T12:12:10', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '901b9b1b-b38f-4e72-a375-3b90bf34d2db'	System	08 Sep 2020 17:12:19
User entered '4'	System	08 Sep 2020 17:12:19

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T12:12:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '901b9b1b-b38f-4e72-a375-3b90bf34d2db'	System	08 Sep 2020 17:12:19
User entered 'None (1)'	System	08 Sep 2020 17:12:19

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T12:12:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '901b9b1b-b38f-4e72-a375-3b90bf34d2db'	System	08 Sep 2020 17:12:19
User entered '08 Sep 2020 12:12'	System	08 Sep 2020 17:12:19

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 11:31'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 14:01'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 14:56'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 2'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:06:54', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1031d812-cd26-4702-9dcb-1a934cdfb93c'	System	10 Sep 2020 00:07:14
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:07:14

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:06:58', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1031d812-cd26-4702-9dcb-1a934cdfb93c'	System	10 Sep 2020 00:07:14
User entered 'No (N)'	System	10 Sep 2020 00:07:14

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:01', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1031d812-cd26-4702-9dcb-1a934cdfb93c'	System	10 Sep 2020 00:07:14
User entered 'No (N)'	System	10 Sep 2020 00:07:14

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:06', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1031d812-cd26-4702-9dcb-1a934cdfb93c'	System	10 Sep 2020 00:07:14
User entered 'None (1)'	System	10 Sep 2020 00:07:14

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1031d812-cd26-4702-9dcb-1a934cdfb93c'	System	10 Sep 2020 00:07:14
User entered '09 Sep 2020 19:07'	System	10 Sep 2020 00:07:14

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 3'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:08:54', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '081f2a5c-0243-4d59-b013-bc17a9992551'	System	11 Sep 2020 01:09:34
User entered 'None (1)'	System	11 Sep 2020 01:09:34

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:04', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '081f2a5c-0243-4d59-b013-bc17a9992551'	System	11 Sep 2020 01:09:34
User entered 'No (N)'	System	11 Sep 2020 01:09:34

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '081f2a5c-0243-4d59-b013-bc17a9992551'	System	11 Sep 2020 01:09:34
User entered 'No (N)'	System	11 Sep 2020 01:09:34

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '081f2a5c-0243-4d59-b013-bc17a9992551'	System	11 Sep 2020 01:09:34
User entered 'None (1)'	System	11 Sep 2020 01:09:34

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:31', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '081f2a5c-0243-4d59-b013-bc17a9992551'	System	11 Sep 2020 01:09:34
User entered '10 Sep 2020 20:09'	System	11 Sep 2020 01:09:34

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 4'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '812c3efc-f0ac-484d-857d-6468960f6b3a'	System	12 Sep 2020 00:12:53
User entered 'None (1)'	System	12 Sep 2020 00:12:53

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '812c3efc-f0ac-484d-857d-6468960f6b3a'	System	12 Sep 2020 00:12:53
User entered 'No (N)'	System	12 Sep 2020 00:12:53

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:44', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '812c3efc-f0ac-484d-857d-6468960f6b3a'	System	12 Sep 2020 00:12:53
User entered 'No (N)'	System	12 Sep 2020 00:12:53

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:46', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '812c3efc-f0ac-484d-857d-6468960f6b3a'	System	12 Sep 2020 00:12:53
User entered 'None (1)'	System	12 Sep 2020 00:12:53

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:12:48', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '812c3efc-f0ac-484d-857d-6468960f6b3a'	System	12 Sep 2020 00:12:53
User entered '11 Sep 2020 19:12'	System	12 Sep 2020 00:12:53

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 5'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:02:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '615fbddb-5e52-4c73-8f1a-e2d441164858'	System	13 Sep 2020 00:03:12
User entered 'None (1)'	System	13 Sep 2020 00:03:12

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:02:57', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '615fbedb-5e52-4c73-8f1a-e2d441164858'	System	13 Sep 2020 00:03:12
User entered 'No (N)'	System	13 Sep 2020 00:03:12

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '615fbadb-5e52-4c73-8f1a-e2d441164858'	System	13 Sep 2020 00:03:12
User entered 'No (N)'	System	13 Sep 2020 00:03:12

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:04', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '615fbdb-5e52-4c73-8f1a-e2d441164858'	System	13 Sep 2020 00:03:12
User entered 'None (1)'	System	13 Sep 2020 00:03:12

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:07', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '615fbedb-5e52-4c73-8f1a-e2d441164858'	System	13 Sep 2020 00:03:12
User entered '12 Sep 2020 19:03'	System	13 Sep 2020 00:03:12

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 6'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:30', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '30dceebd-95d1-40aa-a54e-e4596680cb0d'	System	14 Sep 2020 00:02:44
User entered 'None (1)'	System	14 Sep 2020 00:02:44

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:32', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '30dceebd-95d1-40aa-a54e-e4596680cb0d'	System	14 Sep 2020 00:02:44
User entered 'No (N)'	System	14 Sep 2020 00:02:44

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:35', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '30dceebd-95d1-40aa-a54e-e4596680cb0d'	System	14 Sep 2020 00:02:44
User entered 'No (N)'	System	14 Sep 2020 00:02:44

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '30dceebd-95d1-40aa-a54e-e4596680cb0d'	System	14 Sep 2020 00:02:44
User entered 'None (1)'	System	14 Sep 2020 00:02:44

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:39', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '30dceebd-95d1-40aa-a54e-e4596680cb0d'	System	14 Sep 2020 00:02:44
User entered '13 Sep 2020 19:02'	System	14 Sep 2020 00:02:44

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 7'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:06:38', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '0777ee73-3c37-469a-8c8e-03fafa4db342'	System	15 Sep 2020 00:07:45
User entered 'None (1)'	System	15 Sep 2020 00:07:45

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:06:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '0777ee73-3c37-469a-8c8e-03fafa4db342'	System	15 Sep 2020 00:07:45
User entered 'No (N)'	System	15 Sep 2020 00:07:45

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:06:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '0777ee73-3c37-469a-8c8e-03fafa4db342'	System	15 Sep 2020 00:07:45
User entered 'No (N)'	System	15 Sep 2020 00:07:45

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:38', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '0777ee73-3c37-469a-8c8e-03fafa4db342'	System	15 Sep 2020 00:07:45
User entered 'None (1)'	System	15 Sep 2020 00:07:45

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '0777ee73-3c37-469a-8c8e-03fafa4db342'	System	15 Sep 2020 00:07:45
User entered '14 Sep 2020 19:07'	System	15 Sep 2020 00:07:45

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:38:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'No interference with activity (1)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:37:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'None (0)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:37:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'Some interference with activity (2)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:37:34', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'None (0)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:37:39', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'None (0)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:37:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'None (0)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:38:02', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered 'No (N)'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-08T11:38:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '88621793-2b53-4d08-81ff-c340e1505f1f'	System	08 Sep 2020 16:38:43
User entered '08 Sep 2020 11:38'	System	08 Sep 2020 16:38:43

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 11:31'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 14:01'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Sep 2020 14:56'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 2'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:21', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'None (0)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:27', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'None (0)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'None (0)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:07:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'None (0)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:08:07', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered 'No (N)'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-09T19:08:09', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '728a4c55-7aef-4d51-a32a-0757ab06523c'	System	10 Sep 2020 00:08:12
User entered '09 Sep 2020 19:08'	System	10 Sep 2020 00:08:12

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 3'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:37', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:42', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:49', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'None (0)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'None (0)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'None (0)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:09:59', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered 'No (N)'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-10T20:10:01', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'faa76b19-1a7f-42e9-adb7-9ef4d6777cf2'	System	11 Sep 2020 01:10:06
User entered '10 Sep 2020 20:10'	System	11 Sep 2020 01:10:06

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 4'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'None (0)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:04', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'None (0)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:06', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'None (0)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'None (0)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:10', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'None (0)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'None (0)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:15', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered 'No (N)'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-11T19:13:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fad7b9a8-7e48-41b9-9647-ea76a1cdb6fc'	System	12 Sep 2020 00:13:20
User entered '11 Sep 2020 19:13'	System	12 Sep 2020 00:13:20

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 5'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'None (0)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'None (0)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'None (0)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:16', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'None (0)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'None (0)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'None (0)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:21', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered 'No (N)'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-12T19:03:23', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'de2eba97-34f2-4780-907e-ce3054c2b2a9'	System	13 Sep 2020 00:03:27
User entered '12 Sep 2020 19:03'	System	13 Sep 2020 00:03:27

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 6'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'None (0)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:49', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'None (0)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:52', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'None (0)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'None (0)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'None (0)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:02:58', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'None (0)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:03:02', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered 'No (N)'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-13T19:03:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a6b6febb-a86e-478d-a253-943e5fae2b4f'	System	14 Sep 2020 00:03:11
User entered '13 Sep 2020 19:03'	System	14 Sep 2020 00:03:11

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 7'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:44', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'None (0)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'None (0)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'None (0)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:50', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'None (0)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'None (0)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'None (0)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered 'No (N)'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-09-14T19:07:57', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ed21b22d-377f-4597-99b6-79423fe2d652'	System	15 Sep 2020 00:08:00
User entered '14 Sep 2020 19:07'	System	15 Sep 2020 00:08:00

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:13:18

US3492085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	15 Sep 2020 17:23:57

US3492085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '15 Sep 2020'	Addis Mekonnen (b) (4)	15 Sep 2020 17:23:57

US3492085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	Addis Mekonnen (b) (4)	15 Sep 2020 17:23:57

US3492085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Addis Mekonnen (b) (4)	15 Sep 2020 17:23:57

US3492085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Addis Mekonnen (b) (4)	15 Sep 2020 17:24:02

US3492085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	15 Sep 2020 17:24:02

US3492085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Elena Llinas (b) (4)	22 Sep 2020 19:51:18

US3492085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '22 Sep 2020'	Elena Llinas (b) (4)	22 Sep 2020 19:51:18

US3492085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4)	22 Sep 2020 19:51:18

US3492085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Elena Llinas (b) (4) (b) (4)	22 Sep 2020 19:51:18

US3492085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Elena Llinas (b) (4)	22 Sep 2020 19:51:22

US3492085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	22 Sep 2020 19:51:22

US3492085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Elena Llinas (b) (4)	29 Sep 2020 17:18:42

US3492085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '29 Sep 2020'	Elena Llinas (b) (4)	29 Sep 2020 17:18:42

US3492085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4)	29 Sep 2020 17:48:05
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elena Llinas (b) (4)	29 Sep 2020 17:18:42
	(b) (4)	

US3492085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '29-09-2020 @ 12:18 Left a message'	Elena Llinas (b) (4)	29 Sep 2020 17:18:42

US3492085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Elena Llinas (b) (4)	29 Sep 2020 17:48:10

US3492085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	29 Sep 2020 17:48:10

US3492085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:29:54

US3492085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:29:54

US3492085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:29:54

US3492085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'VISIT2'	System	05 Oct 2020 14:29:54

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '08:40'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '05 Oct 2020 08:40'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:00:28
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 17:49:20
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Oct 2020 17:49:09
User entered '96.5' F	(b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '58'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'bpm'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '12'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'breaths/min'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '91'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:00:31
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs, no defined bp in protocol' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 17:49:36
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Oct 2020 17:49:09
User entered '58'	(b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:36'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '05 Oct 2020 10:36'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'not specified'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '56'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'bpm'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'breaths/min'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '108'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '71'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'mmHg'	System	05 Oct 2020 17:49:09

US3492085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:46

US3492085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:49:46

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User closed query 'Per CDM: Please provide a response for 'Was FSH sample collected?' as this is a required field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 05:07:16
Query 'Per CDM: Please provide a response for 'Was FSH sample collected?' as this is a required field.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	19 Mar 2021 21:26:01
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	19 Mar 2021 21:25:53
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	19 Mar 2021 21:25:53
User opened query 'Per CDM: Please provide a response for 'Was FSH sample collected?' as this is a required field.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:56:12
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	05 Oct 2020 15:40:18

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	30 Oct 2020 16:05:19
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	30 Oct 2020 16:05:19
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 15:42:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 15:42:17
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	05 Oct 2020 15:42:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:42:17
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 15:41:51
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 15:42:17
User entered empty.	System	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:42:17
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:01' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:42:17
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '5 Oct 2020 10:01'	System	05 Oct 2020 15:42:17
User entered empty.	System	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Oct 2020 16:05:19
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'ONCE'	System	05 Oct 2020 15:42:17
User entered empty.	System	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 15:42:17
User entered empty.	System	05 Oct 2020 15:41:51

US3492085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:23

US3492085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:23

US3492085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '09:25'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:23

US3492085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '05 Oct 2020 09:25'	System	05 Oct 2020 17:53:23

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '09:39'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '05 Oct 2020 09:39'	System	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	05 Oct 2020 17:53:40

US3492085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:42:25

US3492085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'I'	System	05 Oct 2020 15:42:25

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:42:49', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '4518162b-a42b-468d-81e2-4444428a6773'	System	05 Oct 2020 15:43:01
User entered 'Yes (Y)'	System	05 Oct 2020 15:43:01

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:42:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '4518162b-a42b-468d-81e2-4444428a6773'	System	05 Oct 2020 15:43:01
User entered '98.3'	System	05 Oct 2020 15:43:01

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:42:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '4518162b-a42b-468d-81e2-4444428a6773'	System	05 Oct 2020 15:43:01
User entered 'No (N)'	System	05 Oct 2020 15:43:01

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:42:59', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '4518162b-a42b-468d-81e2-4444428a6773'	System	05 Oct 2020 15:43:01
User entered '05 Oct 2020 10:42'	System	05 Oct 2020 15:43:01

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 10:21'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 12:51'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 13:46'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 2'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:37', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef93b307-7aff-4d65-a795-a638bc41c12b'	System	06 Oct 2020 21:04:09
User entered 'Yes (Y)'	System	06 Oct 2020 21:04:09

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:03:49', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef93b307-7aff-4d65-a795-a638bc41c12b'	System	06 Oct 2020 21:04:09
User entered '97.8'	System	06 Oct 2020 21:04:09

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:03:52', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef93b307-7aff-4d65-a795-a638bc41c12b'	System	06 Oct 2020 21:04:09
User entered 'No (N)'	System	06 Oct 2020 21:04:09

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:04:05', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ef93b307-7aff-4d65-a795-a638bc41c12b'	System	06 Oct 2020 21:04:09
User entered '06 Oct 2020 16:04'	System	06 Oct 2020 21:04:09

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 3'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:49:21', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62190def-da98-4832-8d2a-fd5703fcadad'	System	08 Oct 2020 04:50:21
User entered 'Yes (Y)'	System	08 Oct 2020 04:50:21

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:13', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62190def-da98-4832-8d2a-fd5703fcadad' User entered '97.5'	System	08 Oct 2020 04:50:21
	System	08 Oct 2020 04:50:21

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:16', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62190def-da98-4832-8d2a-fd5703fcadad'	System	08 Oct 2020 04:50:21
User entered 'No (N)'	System	08 Oct 2020 04:50:21

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62190def-da98-4832-8d2a-fd5703fcadad'	System	08 Oct 2020 04:50:21
User entered '07 Oct 2020 23:50'	System	08 Oct 2020 04:50:21

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 4'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T22:59:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7535c930-7756-42b4-b651-861528cd4d8c'	System	09 Oct 2020 03:59:59
User entered 'Yes (Y)'	System	09 Oct 2020 03:59:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T22:59:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7535c930-7756-42b4-b651-861528cd4d8c' User entered '97.1'	System	09 Oct 2020 03:59:59
	System	09 Oct 2020 03:59:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T22:59:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7535c930-7756-42b4-b651-861528cd4d8c'	System	09 Oct 2020 03:59:59
User entered 'No (N)'	System	09 Oct 2020 03:59:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T22:59:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7535c930-7756-42b4-b651-861528cd4d8c'	System	09 Oct 2020 03:59:59
User entered '08 Oct 2020 22:59'	System	09 Oct 2020 03:59:59

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 5'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:14:43', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '04239f36-f1df-4032-af26-79613547a092'	System	10 Oct 2020 04:14:53
User entered 'Yes (Y)'	System	10 Oct 2020 04:14:53

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:14:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '04239f36-f1df-4032-af26-79613547a092'	System	10 Oct 2020 04:14:53
User entered '98.2'	System	10 Oct 2020 04:14:53

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:14:49', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '04239f36-f1df-4032-af26-79613547a092'	System	10 Oct 2020 04:14:53
User entered 'No (N)'	System	10 Oct 2020 04:14:53

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:14:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '04239f36-f1df-4032-af26-79613547a092'	System	10 Oct 2020 04:14:53
User entered '09 Oct 2020 23:14'	System	10 Oct 2020 04:14:53

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 6'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a771ba85-3f19-4a46-b985-2c460d885d9e'	System	11 Oct 2020 04:26:39
User entered 'Yes (Y)'	System	11 Oct 2020 04:26:39

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:33', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a771ba85-3f19-4a46-b985-2c460d885d9e' User entered '97.7'	System	11 Oct 2020 04:26:39
	System	11 Oct 2020 04:26:39

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:35', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a771ba85-3f19-4a46-b985-2c460d885d9e'	System	11 Oct 2020 04:26:39
User entered 'No (N)'	System	11 Oct 2020 04:26:39

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:38', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a771ba85-3f19-4a46-b985-2c460d885d9e'	System	11 Oct 2020 04:26:39
User entered '10 Oct 2020 23:26'	System	11 Oct 2020 04:26:39

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 7'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62553eec-6458-4e3a-9a1f-2edddcb3197f'	System	12 Oct 2020 03:07:52
User entered 'Yes (Y)'	System	12 Oct 2020 03:07:52

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:32', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62553eec-6458-4e3a-9a1f-2edddcb3197f' User entered '98.2'	System	12 Oct 2020 03:07:52
	System	12 Oct 2020 03:07:52

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62553eec-6458-4e3a-9a1f-2edddcb3197f'	System	12 Oct 2020 03:07:52
User entered 'No (N)'	System	12 Oct 2020 03:07:52

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:48', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '62553eec-6458-4e3a-9a1f-2edddcb3197f'	System	12 Oct 2020 03:07:52
User entered '11 Oct 2020 22:07'	System	12 Oct 2020 03:07:52

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:04', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fb4ace2a-9786-49df-80f4-572850fa8290'	System	05 Oct 2020 15:43:21
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 15:43:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:07', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fb4ace2a-9786-49df-80f4-572850fa8290'	System	05 Oct 2020 15:43:21
User entered 'No (N)'	System	05 Oct 2020 15:43:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:09', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fb4ace2a-9786-49df-80f4-572850fa8290'	System	05 Oct 2020 15:43:21
User entered 'No (N)'	System	05 Oct 2020 15:43:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:15', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fb4ace2a-9786-49df-80f4-572850fa8290'	System	05 Oct 2020 15:43:21
User entered 'None (1)'	System	05 Oct 2020 15:43:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'fb4ace2a-9786-49df-80f4-572850fa8290'	System	05 Oct 2020 15:43:21
User entered '05 Oct 2020 10:43'	System	05 Oct 2020 15:43:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 10:21'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 12:51'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 13:46'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 2'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:01:22', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '18cab3c9-7727-470c-b690-f266c47839ed'	System	06 Oct 2020 21:01:48
User entered 'None (1)'	System	06 Oct 2020 21:01:48

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:01:37', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '18cab3c9-7727-470c-b690-f266c47839ed'	System	06 Oct 2020 21:01:48
User entered 'No (N)'	System	06 Oct 2020 21:01:48

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:01:39', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '18cab3c9-7727-470c-b690-f266c47839ed'	System	06 Oct 2020 21:01:48
User entered 'No (N)'	System	06 Oct 2020 21:01:48

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:01:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '18cab3c9-7727-470c-b690-f266c47839ed'	System	06 Oct 2020 21:01:48
User entered 'None (1)'	System	06 Oct 2020 21:01:48

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:01:44', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '18cab3c9-7727-470c-b690-f266c47839ed'	System	06 Oct 2020 21:01:48
User entered '06 Oct 2020 16:01'	System	06 Oct 2020 21:01:48

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 3'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:27', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '2b55e5ee-9c38-4517-9e59-72dfbb790908'	System	08 Oct 2020 04:50:39
User entered 'None (1)'	System	08 Oct 2020 04:50:39

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '2b55e5ee-9c38-4517-9e59-72dfbb790908'	System	08 Oct 2020 04:50:39
User entered 'No (N)'	System	08 Oct 2020 04:50:39

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:31', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '2b55e5ee-9c38-4517-9e59-72dfbb790908'	System	08 Oct 2020 04:50:39
User entered 'No (N)'	System	08 Oct 2020 04:50:39

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:34', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '2b55e5ee-9c38-4517-9e59-72dfbb790908'	System	08 Oct 2020 04:50:39
User entered 'None (1)'	System	08 Oct 2020 04:50:39

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:37', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '2b55e5ee-9c38-4517-9e59-72dfbb790908'	System	08 Oct 2020 04:50:39
User entered '07 Oct 2020 23:50'	System	08 Oct 2020 04:50:39

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 4'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6e04b2a2-cff2-41b0-824e-0b28c4cf6fbd'	System	09 Oct 2020 04:00:21
User entered 'None (1)'	System	09 Oct 2020 04:00:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:13', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6e04b2a2-cff2-41b0-824e-0b28c4cf6fbd'	System	09 Oct 2020 04:00:21
User entered 'No (N)'	System	09 Oct 2020 04:00:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:15', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6e04b2a2-cff2-41b0-824e-0b28c4cf6fbd'	System	09 Oct 2020 04:00:21
User entered 'No (N)'	System	09 Oct 2020 04:00:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6e04b2a2-cff2-41b0-824e-0b28c4cf6fbd'	System	09 Oct 2020 04:00:21
User entered 'None (1)'	System	09 Oct 2020 04:00:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6e04b2a2-cff2-41b0-824e-0b28c4cf6fbd'	System	09 Oct 2020 04:00:21
User entered '08 Oct 2020 23:00'	System	09 Oct 2020 04:00:21

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 5'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '24969793-6d13-4fc8-a3ad-f4d2703add8f'	System	10 Oct 2020 04:13:54
User entered 'None (1)'	System	10 Oct 2020 04:13:54

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:45', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '24969793-6d13-4fc8-a3ad-f4d2703add8f'	System	10 Oct 2020 04:13:54
User entered 'No (N)'	System	10 Oct 2020 04:13:54

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:48', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '24969793-6d13-4fc8-a3ad-f4d2703add8f'	System	10 Oct 2020 04:13:54
User entered 'No (N)'	System	10 Oct 2020 04:13:54

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:50', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '24969793-6d13-4fc8-a3ad-f4d2703add8f'	System	10 Oct 2020 04:13:54
User entered 'None (1)'	System	10 Oct 2020 04:13:54

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:52', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '24969793-6d13-4fc8-a3ad-f4d2703add8f'	System	10 Oct 2020 04:13:54
User entered '09 Oct 2020 23:13'	System	10 Oct 2020 04:13:54

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 6'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c5faa577-ff41-4904-a864-8d9a530a6fad'	System	11 Oct 2020 04:26:49
User entered 'None (1)'	System	11 Oct 2020 04:26:49

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:42', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c5faa577-ff41-4904-a864-8d9a530a6fad'	System	11 Oct 2020 04:26:49
User entered 'No (N)'	System	11 Oct 2020 04:26:49

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:44', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c5faa577-ff41-4904-a864-8d9a530a6fad'	System	11 Oct 2020 04:26:49
User entered 'No (N)'	System	11 Oct 2020 04:26:49

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:46', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c5faa577-ff41-4904-a864-8d9a530a6fad'	System	11 Oct 2020 04:26:49
User entered 'None (1)'	System	11 Oct 2020 04:26:49

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:48', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c5faa577-ff41-4904-a864-8d9a530a6fad'	System	11 Oct 2020 04:26:49
User entered '10 Oct 2020 23:26'	System	11 Oct 2020 04:26:49

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 7'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f17d71fe-e6ec-4d61-a716-2d94edf1b0e4'	System	12 Oct 2020 03:08:03
User entered 'None (1)'	System	12 Oct 2020 03:08:03

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f17d71fe-e6ec-4d61-a716-2d94edf1b0e4'	System	12 Oct 2020 03:08:03
User entered 'No (N)'	System	12 Oct 2020 03:08:03

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f17d71fe-e6ec-4d61-a716-2d94edf1b0e4'	System	12 Oct 2020 03:08:03
User entered 'No (N)'	System	12 Oct 2020 03:08:03

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:07:58', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f17d71fe-e6ec-4d61-a716-2d94edf1b0e4'	System	12 Oct 2020 03:08:03
User entered 'None (1)'	System	12 Oct 2020 03:08:03

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:01', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f17d71fe-e6ec-4d61-a716-2d94edf1b0e4'	System	12 Oct 2020 03:08:03
User entered '11 Oct 2020 22:08'	System	12 Oct 2020 03:08:03

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:21', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'No interference with activity (1)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:24', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'None (0)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:26', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'None (0)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'None (0)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:30', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'None (0)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:32', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'None (0)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered 'No (N)'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-05T10:43:39', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'efec259d-2092-4134-9fa1-30f03d2f485c'	System	05 Oct 2020 15:43:40
User entered '05 Oct 2020 10:43'	System	05 Oct 2020 15:43:40

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 10:21'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 12:51'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '05 Oct 2020 13:46'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 2'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:01:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'None (0)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'None (0)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:10', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'None (0)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'None (0)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'None (0)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:20', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'None (0)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:22', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered 'No (N)'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-06T16:02:24', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1f29ed4c-dbb8-4ebf-99e6-96d965516e9c'	System	06 Oct 2020 21:02:26
User entered '06 Oct 2020 16:02'	System	06 Oct 2020 21:02:26

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 3'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:44', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'None (0)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'None (0)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:49', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'None (0)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'None (0)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'None (0)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'None (0)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:50:59', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered 'No (N)'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-07T23:51:01', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7d4c65d1-52a5-4342-8e2c-60ef081ec159'	System	08 Oct 2020 04:51:03
User entered '07 Oct 2020 23:51'	System	08 Oct 2020 04:51:03

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 4'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'No interference with activity (1)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:26', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'None (0)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'None (0)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'None (0)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:31', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'None (0)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:32', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'None (0)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:34', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered 'No (N)'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-08T23:00:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '08757a02-5f5f-4ea7-a28f-a18cfa032a5f'	System	09 Oct 2020 04:00:39
User entered '08 Oct 2020 23:00'	System	09 Oct 2020 04:00:39

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 5'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:23', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'None (0)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:24', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'None (0)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:26', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'None (0)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:27', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'None (0)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'None (0)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:30', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'None (0)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:36', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered 'No (N)'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-09T23:13:38', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7e7c862f-9a77-4311-9d66-21a009d5207c'	System	10 Oct 2020 04:13:41
User entered '09 Oct 2020 23:13'	System	10 Oct 2020 04:13:41

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 6'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:50', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'None (0)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'None (0)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'None (0)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:54', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'None (0)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:55', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'None (0)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'None (0)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:26:58', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered 'No (N)'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-10T23:27:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '592af53e-9b36-48ed-8fd9-d5b0050a6491'	System	11 Oct 2020 04:27:02
User entered '10 Oct 2020 23:27'	System	11 Oct 2020 04:27:02

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	05 Oct 2020 15:42:17
User entered 'Day 7'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:06', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'None (0)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'None (0)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'No interference with activity (1)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'None (0)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:21', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'No interference with activity (1)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:35', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered 'No (N)'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-11T22:08:37', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '644148bf-b5ce-4bbb-b843-db0475c12b6b'	System	12 Oct 2020 03:08:42
User entered '11 Oct 2020 22:08'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 15:42:17

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	12 Oct 2020 03:08:42
User entered 'Day 8'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:57:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:07', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3985fe50-2989-428c-8749-f28f70267e54'	System	13 Oct 2020 03:40:14
User entered 'No interference with activity (1)'	System	13 Oct 2020 03:40:14

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:10', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3985fe50-2989-428c-8749-f28f70267e54'	System	13 Oct 2020 03:40:14
User entered '12 Oct 2020 22:40'	System	13 Oct 2020 03:40:14

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	12 Oct 2020 03:08:42
User entered 'Day 9'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:57:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-13T19:49:57', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '391acfa3-fd3d-4346-b5a0-83dbc5a6d70b'	System	14 Oct 2020 00:50:04
User entered 'None (0)'	System	14 Oct 2020 00:50:04

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-13T19:49:59', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '391acfa3-fd3d-4346-b5a0-83dbc5a6d70b'	System	14 Oct 2020 00:50:04
User entered '13 Oct 2020 19:49'	System	14 Oct 2020 00:50:04

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	12 Oct 2020 03:08:42
User entered 'Day 8'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 07:57:48

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '10ed225f-7aa7-4e62-8795-e4ed89551c47'	System	13 Oct 2020 03:40:20
User entered 'None (0)'	System	13 Oct 2020 03:40:20

US3492085

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:16', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '10ed225f-7aa7-4e62-8795-e4ed89551c47'	System	13 Oct 2020 03:40:20
User entered '12 Oct 2020 22:40'	System	13 Oct 2020 03:40:20

US3492085

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	12 Oct 2020 03:08:42
User entered 'Day 8'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 07:57:48

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'b20d6d97-79fb-40b2-9acb-02768b77c82e'	System	13 Oct 2020 03:40:23
User entered 'None (0)'	System	13 Oct 2020 03:40:23

US3492085

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:21', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'b20d6d97-79fb-40b2-9acb-02768b77c82e'	System	13 Oct 2020 03:40:23
User entered '12 Oct 2020 22:40'	System	13 Oct 2020 03:40:23

US3492085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	12 Oct 2020 03:08:42
User entered 'Day 8'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '44b5dba4-01ac-4a56-9889-d10a65c40d71'	System	13 Oct 2020 03:40:32
User entered 'Yes (Y)'	System	13 Oct 2020 03:40:32

US3492085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-10-12T22:40:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '44b5dba4-01ac-4a56-9889-d10a65c40d71'	System	13 Oct 2020 03:40:32
User entered '12 Oct 2020 22:40'	System	13 Oct 2020 03:40:32

US3492085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 03:08:42

US3492085

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 07:57:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 03:08:42

US3492085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	21 Oct 2020 20:22:31
	(b) (4)	

US3492085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '13 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 20:22:31

US3492085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 20:22:31

US3492085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 20:22:31

US3492085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	21 Oct 2020 19:19:16
	(b) (4)	

US3492085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	21 Oct 2020 19:19:16

US3492085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	21 Oct 2020 19:19:42
	(b) (4)	

US3492085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '20 Oct 2020'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:19:42

US3492085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:19:42

US3492085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	21 Oct 2020 19:19:42
	(b) (4)	

US3492085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	21 Oct 2020 19:20:15
	(b) (4)	

US3492085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	21 Oct 2020 19:20:15

US3492085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Michelle Agnoli (b) (4)	30 Oct 2020 20:04:47

US3492085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '27 Oct 2020'	Michelle Agnoli (b) (4)	30 Oct 2020 20:04:47

US3492085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	Michelle Agnoli (b) (4)	30 Oct 2020 20:04:47

US3492085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Michelle Agnoli (b) (4)	30 Oct 2020 20:04:47

US3492085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Michelle Agnoli (b) (4)	30 Oct 2020 20:04:53

US3492085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	30 Oct 2020 20:04:53

US3492085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
Signature has been broken.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:03
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:03
	(b) (4)	
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:40:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 13:03:08
Query 'Data is required. Please complete.' answered with 'midway through visit, clinicial decided subject had possible COVID symptoms, changed to illness visit per CTM guidance' (Site from System).	Andrea Wendrow (b) (4)	14 Nov 2020 20:45:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 20:43:33
User entered empty; reason for change New Information	Andrea Wendrow (b) (4)	14 Nov 2020 20:43:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 16:51:17

US3492085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:40:08
User entered empty; reason for change New Information	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:43:33
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 16:51:17

US3492085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:40:08
User entered empty; reason for change New Information	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:43:33
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Nov 2020 16:51:17

US3492085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered 'VISIT3'	System	19 Mar 2021 20:49:03
User entered empty.	System	14 Nov 2020 20:43:33
User entered 'VISIT3'	System	02 Nov 2020 16:51:17

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	19 Mar 2021 20:49:19

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37

US3492085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37

US3492085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'No (N)'	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:27

US3492085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 20:49:27

US3492085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'No (N)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:34

US3492085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:34

US3492085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 20:49:34

US3492085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered empty.	System	19 Mar 2021 20:49:34

US3492085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 16:51:50

US3492085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:37
User entered '1'	System	02 Nov 2020 16:51:50

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 64'	System	08 Sep 2020 16:13:18

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:49:32', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered 'Yes (Y)'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:49:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered 'No (N)'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:49:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered 'Yes (Y)'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '1'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '1'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '1'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '1'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:12', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '0'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered 'No (N)'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-09T16:50:28', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce7f89cb-4314-44f7-9d20-07115328f7a5'	System	09 Nov 2020 22:50:44
User entered '09 Nov 2020 16:50:28'	System	09 Nov 2020 22:50:44

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 16:13:18

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered 'Day 71'	System	08 Sep 2020 16:13:18

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-16T00:19:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'dd4c3794-c647-49aa-a139-1b3c245eac02'	System	16 Nov 2020 06:19:25
User entered 'No (N)'	System	16 Nov 2020 06:19:25

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-16T00:19:16', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'dd4c3794-c647-49aa-a139-1b3c245eac02'	System	16 Nov 2020 06:19:25
User entered 'No (N)'	System	16 Nov 2020 06:19:25

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-16T00:19:20', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'dd4c3794-c647-49aa-a139-1b3c245eac02'	System	16 Nov 2020 06:19:25
User entered '16 Nov 2020 00:19:20'	System	16 Nov 2020 06:19:25

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 16:13:18

US3492085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:32
Data entry locked.	System	08 Sep 2020 16:13:18
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 16:13:18

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-11-23T09:59:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1106da77-4286-4d37-ac10-7e8f5a1fbe46'	System	23 Nov 2020 15:59:28
User entered 'No (N)'	System	23 Nov 2020 15:59:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2020-11-23T09:59:22', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1106da77-4286-4d37-ac10-7e8f5a1fbe46'	System	23 Nov 2020 15:59:28
User entered 'No (N)'	System	23 Nov 2020 15:59:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-23T09:59:25', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '1106da77-4286-4d37-ac10-7e8f5a1fbe46'	System	23 Nov 2020 15:59:28
User entered '23 Nov 2020 09:59:25'	System	23 Nov 2020 15:59:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-11-30T11:23:06', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'cd2c37a0-5f54-406b-8945-7e6b20e3c984'	System	30 Nov 2020 17:23:41
User entered 'Yes (Y)'	System	30 Nov 2020 17:23:41

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2020-11-30T11:23:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'cd2c37a0-5f54-406b-8945-7e6b20e3c984'	System	30 Nov 2020 17:23:41
User entered 'No (N)'	System	30 Nov 2020 17:23:41

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-11-30T11:23:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'cd2c37a0-5f54-406b-8945-7e6b20e3c984'	System	30 Nov 2020 17:23:41
User entered 'No (N)'	System	30 Nov 2020 17:23:41

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-11-30T11:23:23', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'cd2c37a0-5f54-406b-8945-7e6b20e3c984'	System	30 Nov 2020 17:23:41
User entered 'Yes (Y)'	System	30 Nov 2020 17:23:41

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Please 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 (86d7398224637027)', Time: '2020-11-30T11:23:26', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'cd2c37a0-5f54-406b-8945-7e6b20e3c984'	System	30 Nov 2020 17:23:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 17:23:41

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-11-30T11:23:29', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'cd2c37a0-5f54-406b-8945-7e6b20e3c984'	System	30 Nov 2020 17:23:41
User entered '30 Nov 2020 11:23:29'	System	30 Nov 2020 17:23:41

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-12-07T12:06:09', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '85661213-b38e-40f8-ae3c-28a5f3a362f6'	System	07 Dec 2020 18:06:23
User entered 'No (N)'	System	07 Dec 2020 18:06:23

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2020-12-07T12:06:13', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '85661213-b38e-40f8-ae3c-28a5f3a362f6'	System	07 Dec 2020 18:06:23
User entered 'No (N)'	System	07 Dec 2020 18:06:23

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-12-07T12:06:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '85661213-b38e-40f8-ae3c-28a5f3a362f6'	System	07 Dec 2020 18:06:23
User entered '07 Dec 2020 12:06:19'	System	07 Dec 2020 18:06:23

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-12-14T16:09:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f599943e-ff04-4b74-a1a3-3a8a10a45ba6'	System	14 Dec 2020 22:09:26
User entered 'No (N)'	System	14 Dec 2020 22:09:26

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2020-12-14T16:09:20', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f599943e-ff04-4b74-a1a3-3a8a10a45ba6'	System	14 Dec 2020 22:09:26
User entered 'No (N)'	System	14 Dec 2020 22:09:26

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-12-14T16:09:22', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f599943e-ff04-4b74-a1a3-3a8a10a45ba6'	System	14 Dec 2020 22:09:26
User entered '14 Dec 2020 16:09:22'	System	14 Dec 2020 22:09:26

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-12-21T11:25:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '748355af-279e-40f4-9042-56b24418dca6'	System	21 Dec 2020 17:25:58
User entered 'No (N)'	System	21 Dec 2020 17:25:58

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2020-12-21T11:25:50', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '748355af-279e-40f4-9042-56b24418dca6'	System	21 Dec 2020 17:25:58
User entered 'No (N)'	System	21 Dec 2020 17:25:58

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-12-21T11:25:52', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '748355af-279e-40f4-9042-56b24418dca6'	System	21 Dec 2020 17:25:58
User entered '21 Dec 2020 11:25:52'	System	21 Dec 2020 17:25:58

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2020-12-28T12:18:51', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '240f236d-96e5-4e04-acd0-c4437ac91b2e'	System	28 Dec 2020 18:18:59
User entered 'No (N)'	System	28 Dec 2020 18:18:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2020-12-28T12:18:54', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '240f236d-96e5-4e04-acd0-c4437ac91b2e'	System	28 Dec 2020 18:18:59
User entered 'No (N)'	System	28 Dec 2020 18:18:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2020-12-28T12:18:56', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '240f236d-96e5-4e04-acd0-c4437ac91b2e' User entered '28 Dec 2020 12:18:56'	System	28 Dec 2020 18:18:59
	System	28 Dec 2020 18:18:59

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2021-01-11T07:10:53', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd699cbf5-c7b3-4e86-a2f4-e975da4d6bd4'	System	11 Jan 2021 13:11:12
User entered 'No (N)'	System	11 Jan 2021 13:11:12

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2021-01-11T07:11:05', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd699cbf5-c7b3-4e86-a2f4-e975da4d6bd4'	System	11 Jan 2021 13:11:12
User entered 'No (N)'	System	11 Jan 2021 13:11:12

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2021-01-11T07:11:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'd699cbf5-c7b3-4e86-a2f4-e975da4d6bd4'	System	11 Jan 2021 13:11:12
User entered '11 Jan 2021 07:11:08'	System	11 Jan 2021 13:11:12

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2021-01-17T17:53:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6d67e3fc-bd38-449c-8cc5-e9a173c7b8d3'	System	17 Jan 2021 23:53:21
User entered 'No (N)'	System	17 Jan 2021 23:53:21

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2021-01-17T17:53:15', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6d67e3fc-bd38-449c-8cc5-e9a173c7b8d3'	System	17 Jan 2021 23:53:21
User entered 'No (N)'	System	17 Jan 2021 23:53:21

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2021-01-17T17:53:18', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '6d67e3fc-bd38-449c-8cc5-e9a173c7b8d3'	System	17 Jan 2021 23:53:21
User entered '17 Jan 2021 17:53:18'	System	17 Jan 2021 23:53:21

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2021-01-23T07:19:38', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3c950f41-00fd-4e3e-a1d7-bec3bb87df79'	System	23 Jan 2021 13:19:51
User entered 'No (N)'	System	23 Jan 2021 13:19:51

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (86d7398224637027)', Time: '2021-01-23T07:19:41', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3c950f41-00fd-4e3e-a1d7-bec3bb87df79'	System	23 Jan 2021 13:19:51
User entered 'No (N)'	System	23 Jan 2021 13:19:51

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2021-01-23T07:19:47', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '3c950f41-00fd-4e3e-a1d7-bec3bb87df79' User entered '23 Jan 2021 07:19:47'	System	23 Jan 2021 13:19:51
	System	23 Jan 2021 13:19:51

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (86d7398224637027)', Time: '2021-01-29T20:16:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a0081a97-a441-4d6b-aa71-2f0b57ee91ec'	System	30 Jan 2021 02:16:19
User entered 'No (N)'	System	30 Jan 2021 02:16:19

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (86d7398224637027)', Time: '2021-01-29T20:16:14', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a0081a97-a441-4d6b-aa71-2f0b57ee91ec'	System	30 Jan 2021 02:16:19
User entered 'No (N)'	System	30 Jan 2021 02:16:19

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (86d7398224637027)', Time: '2021-01-29T20:16:16', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a0081a97-a441-4d6b-aa71-2f0b57ee91ec'	System	30 Jan 2021 02:16:19
User entered '29 Jan 2021 20:16:16'	System	30 Jan 2021 02:16:19

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-02-08T22:34:06', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f15f6dfc-c79b-422d-abc1-f123ba7a459b'	System	09 Feb 2021 04:34:14
User entered 'No (N)'	System	09 Feb 2021 04:34:14

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-02-08T22:34:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f15f6dfc-c79b-422d-abc1-f123ba7a459b'	System	09 Feb 2021 04:34:14
User entered 'No (N)'	System	09 Feb 2021 04:34:14

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-02-08T22:34:11', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'f15f6dfc-c79b-422d-abc1-f123ba7a459b'	System	09 Feb 2021 04:34:14
User entered '08 Feb 2021 22:34:11'	System	09 Feb 2021 04:34:14

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-02-11T21:46:17', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'afd2ca7f-1714-46e7-9e50-cb79a9096d1f'	System	12 Feb 2021 03:46:24
User entered 'No (N)'	System	12 Feb 2021 03:46:24

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-02-11T21:46:19', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'afd2ca7f-1714-46e7-9e50-cb79a9096d1f'	System	12 Feb 2021 03:46:24
User entered 'No (N)'	System	12 Feb 2021 03:46:24

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-02-11T21:46:22', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'afd2ca7f-1714-46e7-9e50-cb79a9096d1f' User entered '11 Feb 2021 21:46:22'	System	12 Feb 2021 03:46:24

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-02-20T00:03:08', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'aeef7f14-355d-482c-821e-05bb4cc4e934'	System	20 Feb 2021 06:03:20
User entered 'No (N)'	System	20 Feb 2021 06:03:20

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-02-20T00:03:10', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'aeef7f14-355d-482c-821e-05bb4cc4e934'	System	20 Feb 2021 06:03:20
User entered 'No (N)'	System	20 Feb 2021 06:03:20

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-02-20T00:03:16', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'aeef7f14-355d-482c-821e-05bb4cc4e934'	System	20 Feb 2021 06:03:20
User entered '20 Feb 2021 00:03:16'	System	20 Feb 2021 06:03:20

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-02-26T10:54:03-06:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce5ee3cc-c892-4542-89b2-b27e856b988f'	System	26 Feb 2021 16:54:16
User entered 'No (N)'	System	26 Feb 2021 16:54:16

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-02-26T10:54:06-06:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce5ee3cc-c892-4542-89b2-b27e856b988f' User entered 'No (N)'	System	26 Feb 2021 16:54:16
	System	26 Feb 2021 16:54:16

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-02-26T10:54:10-06:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'ce5ee3cc-c892-4542-89b2-b27e856b988f' User entered '26 Feb 2021 10:54:10'	System	26 Feb 2021 16:54:16
	System	26 Feb 2021 16:54:16

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-03-14T09:35:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a41b3f9a-64c1-4e4d-8f09-78a1616f6872'	System	14 Mar 2021 14:35:28
User entered 'No (N)'	System	14 Mar 2021 14:35:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-03-14T09:35:21-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a41b3f9a-64c1-4e4d-8f09-78a1616f6872'	System	14 Mar 2021 14:35:28
User entered 'No (N)'	System	14 Mar 2021 14:35:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-14T09:35:23-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'a41b3f9a-64c1-4e4d-8f09-78a1616f6872' User entered '14 Mar 2021 09:35:23'	System	14 Mar 2021 14:35:28
	System	14 Mar 2021 14:35:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-03-19T08:46:54-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered 'Yes (Y)'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-03-19T08:46:59-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered 'Yes (Y)'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Please 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 (c277b0f7f02b5905)', Time: '2021-03-19T08:47:04-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-03-19T08:47:10-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered 'Yes (Y)'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31' User entered '0'	System	19 Mar 2021 13:47:47
	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '1'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '1'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31' User entered '0'	System	19 Mar 2021 13:47:47
	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:17-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '0'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Please 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 (c277b0f7f02b5905)', Time: '2021-03-19T08:47:19-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-03-19T08:47:28-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered 'No (N)'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-19T08:47:31-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '7dd3f343-5943-4e9b-866e-97abc5592a31'	System	19 Mar 2021 13:47:47
User entered '19 Mar 2021 08:47:31'	System	19 Mar 2021 13:47:47

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-03-29T10:37:50-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '680e7664-bf7d-4bf1-a1aa-6cd530777137'	System	29 Mar 2021 15:37:58
User entered 'No (N)'	System	29 Mar 2021 15:37:58

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-03-29T10:37:53-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '680e7664-bf7d-4bf1-a1aa-6cd530777137'	System	29 Mar 2021 15:37:58
User entered 'No (N)'	System	29 Mar 2021 15:37:58

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-29T10:37:55-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '680e7664-bf7d-4bf1-a1aa-6cd530777137'	System	29 Mar 2021 15:37:58
User entered '29 Mar 2021 10:37:55'	System	29 Mar 2021 15:37:58

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-04-01T07:21:19-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '418677b1-468e-4c4e-926f-b24d5deeb54a' User entered 'No (N)'	System	01 Apr 2021 12:21:28
	System	01 Apr 2021 12:21:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-04-01T07:21:22-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '418677b1-468e-4c4e-926f-b24d5deeb54a' User entered 'No (N)'	System	01 Apr 2021 12:21:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-04-01T07:21:25-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '418677b1-468e-4c4e-926f-b24d5deeb54a'	System	01 Apr 2021 12:21:28
User entered '01 Apr 2021 07:21:25'	System	01 Apr 2021 12:21:28

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-04-08T16:00:24-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '077fb939-5390-4fce-a90a-68f3d5ced033'	System	08 Apr 2021 21:00:42
User entered 'No (N)'	System	08 Apr 2021 21:00:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-04-08T16:00:26-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '077fb939-5390-4fce-a90a-68f3d5ced033'	System	08 Apr 2021 21:00:42
User entered 'No (N)'	System	08 Apr 2021 21:00:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-04-08T16:00:28-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '077fb939-5390-4fce-a90a-68f3d5ced033'	System	08 Apr 2021 21:00:42
User entered '08 Apr 2021 16:00:28'	System	08 Apr 2021 21:00:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-04-23T19:31:33-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c1810f47-a294-4740-b291-ee18d5e1bc56'	System	24 Apr 2021 00:31:43
User entered 'No (N)'	System	24 Apr 2021 00:31:43

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-04-23T19:31:35-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c1810f47-a294-4740-b291-ee18d5e1bc56'	System	24 Apr 2021 00:31:43
User entered 'No (N)'	System	24 Apr 2021 00:31:43

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-04-23T19:31:37-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: 'c1810f47-a294-4740-b291-ee18d5e1bc56'	System	24 Apr 2021 00:31:43
User entered '23 Apr 2021 19:31:37'	System	24 Apr 2021 00:31:43

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-05-01T05:15:46-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '90f40b9e-b578-4391-81bc-040890ce8c38'	System	01 May 2021 10:16:22
User entered 'Yes (Y)'	System	01 May 2021 10:16:22

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

Have you been exposed to someone with 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 (c277b0f7f02b5905)', Time: '2021-05-01T05:15:51-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '90f40b9e-b578-4391-81bc-040890ce8c38'	System	01 May 2021 10:16:22
User entered 'No (N)'	System	01 May 2021 10:16:22

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-05-01T05:15:56-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '90f40b9e-b578-4391-81bc-040890ce8c38'	System	01 May 2021 10:16:22
User entered 'No (N)'	System	01 May 2021 10:16:22

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[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 (c277b0f7f02b5905)', Time: '2021-05-01T05:16:02-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '90f40b9e-b578-4391-81bc-040890ce8c38'	System	01 May 2021 10:16:22
User entered 'Yes (Y)'	System	01 May 2021 10:16:22

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Please 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 (c277b0f7f02b5905)', Time: '2021-05-01T05:16:09-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '90f40b9e-b578-4391-81bc-040890ce8c38'	System	01 May 2021 10:16:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 May 2021 10:16:22

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-05-01T05:16:11-05:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '90f40b9e-b578-4391-81bc-040890ce8c38'	System	01 May 2021 10:16:22
User entered '01 May 2021 05:16:11'	System	01 May 2021 10:16:22

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:03:42

US3492085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:03:42
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:03:42

US3492085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:57:48

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)	24 Apr 2021 13:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-02T07:25:12-06:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '03406c34-79a2-4464-91d5-81330ad29072'	System	02 Mar 2021 13:25:18
User entered 'No (N)'	System	02 Mar 2021 13:25:18

US3492085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:57:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:14:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c277b0f7f02b5905)', Time: '2021-03-02T07:25:15-06:00', User OID: 'PatientReportedOutcome (US3492085)', ODM File OID: '03406c34-79a2-4464-91d5-81330ad29072'	System	02 Mar 2021 13:25:18
User entered '02 Mar 2021 07:25:15'	System	02 Mar 2021 13:25:18

US3492085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	Marla Schwarber (b) (4)	25 Mar 2021 19:41:36

US3492085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '30 Nov 2020'	Marla Schwarber (b) (4)	25 Mar 2021 19:41:36

US3492085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Marla Schwarber (b) (4)	25 Mar 2021 19:41:36

US3492085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) Marla Schwarber (b) (4)	25 Mar 2021 19:41:36

US3492085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:01:23

US3492085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:36:19
User entered 'I'	System	31 Dec 2020 17:01:23

US3492085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:16:02

US3492085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:16:02

US3492085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:16:02

US3492085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:16:02

US3492085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:16:13

US3492085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User entered 'I'	System	31 Dec 2020 18:16:13

US3492085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:46:07

US3492085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:46:07

US3492085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:46:07

US3492085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:46:07

US3492085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:46:16

US3492085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User entered 'I'	System	01 Feb 2021 18:46:16

US3492085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	02 Mar 2021 15:33:17

US3492085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '2 Mar 2021'	Nia Moragne-O'Neal (b) (4)	02 Mar 2021 15:33:17

US3492085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	02 Mar 2021 15:33:17

US3492085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	Nia Moragne-O'Neal (b) (4)	02 Mar 2021 15:33:17

US3492085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	02 Mar 2021 15:33:21

US3492085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:26:18
User entered 'I'	System	02 Mar 2021 15:33:21

US3492085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
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	15 Apr 2021 20:24:25
User entered 'Yes (Y)' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	15 Apr 2021 20:24:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	15 Apr 2021 16:22:28
	Andrea Wendrow (b) (4)	15 Apr 2021 16:22:28
	(b) (4)	

US3492085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '20 Mar 2021' reason for change: Per Query Resolution	(b) (4)	
	Michelle Agnoli (b) (4)	15 Apr 2021 20:24:25
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	15 Apr 2021 16:22:28
	(b) (4)	

US3492085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Clinic (Clinic)' reason for change: Per Query Resolution	(b) (4)	
User entered empty.	Michelle Agnoli (b) (4)	15 Apr 2021 20:24:25
	(b) (4)	
	Andrea Wendrow (b) (4)	15 Apr 2021 16:22:28
	(b) (4)	

US3492085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered 'VISIT4'	System	15 Apr 2021 20:24:25
User entered empty.	System	15 Apr 2021 16:22:28

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	15 Apr 2021 20:27:44
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	15 Apr 2021 20:27:44
User entered '20 Mar 2021' reason for change: Per Query Resolution	Michelle Agnoli (b) (4)	15 Apr 2021 20:27:44
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	15 Apr 2021 20:26:32
User entered '13 Mar 2021'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '13:05'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered '20 Mar 2021 13:05'	System	15 Apr 2021 20:27:44
User entered '13 Mar 2021 13:05'	System	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '97.8' F	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Other (Other)'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'tympanic'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '61'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered 'bpm'	System	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '17'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered 'breaths/min'	System	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '97'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered 'mmHg'	System	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '61'	Michelle Agnoli (b) (4)	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered 'mmHg'	System	15 Apr 2021 20:26:32

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23

US3492085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23

US3492085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	(b) (4) Michelle Agnoli (b) (4)	15 Apr 2021 20:28:13

US3492085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '20 Mar 2021'	Michelle Agnoli (b) (4)	15 Apr 2021 20:28:13

US3492085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	(b) (4) Michelle Agnoli (b) (4)	15 Apr 2021 20:30:08

US3492085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '20 Mar 2021'	(b) (4) Michelle Agnoli (b) (4)	15 Apr 2021 20:30:08

US3492085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '13:08'	(b) (4) Michelle Agnoli (b) (4)	15 Apr 2021 20:30:08

US3492085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered '20 Mar 2021 13:08'	System	15 Apr 2021 20:30:08

US3492085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	(b) (4) Michelle Agnoli (b) (4)	15 Apr 2021 20:28:40

US3492085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:30:23
User entered 'I'	System	15 Apr 2021 20:28:40

US3492085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:05:03

US3492085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User entered '3 May 2021'	(b) (4), (b) (6)	03 May 2021 22:05:03

US3492085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 May 2021 22:05:03

US3492085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:05:03

US3492085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:05:11

US3492085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 22:05:11

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:41:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:14

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:41:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:00'	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:14

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:41:15
User entered '2 Nov 2020 10:00'	System	12 Dec 2020 18:17:14

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:41:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:14

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:41:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	12 Dec 2020 18:17:14

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[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 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[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 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD Central Lab has this swab sample labelled as Unscheduled. Could you please clarify the correct visit name so that it can be reconciled. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 08:20:42
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD Central Lab has this swab sample labelled as Unscheduled. Could you please clarify the correct visit name so that it can be reconciled. Thank you.' answered with 'The swab was taken from an unscheduled visit as subject c/o of COVID like symptoms during what would have been her D57 visit. As bloods have been drawn, per epip #411405, all labwork should be considered as illness visit. ' (Site from DM).	Andrea Wendrow (b) (4)	26 Mar 2021 16:01:30
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD Central Lab has this swab sample labelled as Unscheduled. Could you please clarify the correct visit name so that it can be reconciled. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:45:44
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2 Nov 2020'	Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[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 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Andrea Wendrow (b) (4)	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:07
User entered '0'	System	12 Dec 2020 18:17:44

US3492085

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:57:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:42:16
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:21:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:08
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 19-Mar-2021 is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, and if Yes, please consider updating Swab data in the COVID Diagnostic form. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:44:23
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 19-Mar-2021 is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, and if Yes, please consider updating Swab data in the COVID Diagnostic form. Else clarify, thank you.' answered with 'because we just received report today! done!' (Site from DM).	Andrea Wendrow (b) (4)	26 Mar 2021 16:03:32
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 19-Mar-2021 is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, and if Yes, please consider updating Swab data in the COVID Diagnostic form. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:52:44
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '19 Mar 2021'	Andrea Wendrow (b) (4)	19 Mar 2021 21:28:32

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:08
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '09:42'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:28:32

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:08
User entered '19 Mar 2021 09:42'	System	19 Mar 2021 21:28:32

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:08
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Safety Call (Safety Call)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:28:32

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:57:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:08
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:28:32

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 1 (Day 1)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
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	19 Mar 2021 21:42:02
User entered '14 Mar 2021' reason for change: Data Entry Error	System	19 Mar 2021 21:42:02
User opened query 'Data is required. Please complete.' (Site from System).	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
User entered empty.	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Mar 2021 21:42:02
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	19 Mar 2021 21:42:02
User entered empty.	System	19 Mar 2021 21:40:18

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Mar 2021 21:42:02
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	19 Mar 2021 21:42:02
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	19 Mar 2021 21:40:18
	(b) (4)	

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 2 (Day 2)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '15 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:43:12

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 3 (Day 3)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '16 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:45:02

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 4 (Day 4)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '17 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:46:07

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 5 (Day 5)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '18 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:47:26

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 6 (Day 6)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '19 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '97'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98.7' F	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4)	19 Mar 2021 21:48:42

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 7 (Day 7)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '20 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '100'	Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98.3' F	Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:55:33

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 8 (Day 8)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '21 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '99'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98' F	Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Moderate (Moderate)'	(b) (4) Andrea Wendrow (b) (4)	21 Mar 2021 22:56:58

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '99'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:35:52

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '100'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:37:48

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 11 (Day 11)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '24 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '99'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '97.5' F	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Severe (Severe)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Day 12 (Day 12)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '25 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '99'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User entered '%'	System	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '97' F	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 07:57:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Severe (Severe)'	(b) (4) Andrea Wendrow (b) (4)	25 Mar 2021 23:33:20

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '19 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[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 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[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 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '19 Mar 2021'	(b) (4) Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered empty.	Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[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 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'No (N)'	Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered empty.	Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered empty.	Andrea Wendrow (b) (4)	26 Mar 2021 15:53:47

US3492085

Folder: Covid-19 Assessment 19 Mar 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:57:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:40:47
User entered '0'	System	26 Mar 2021 15:53:47

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 20:42:41

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 20:42:41

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:42:41
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '21 Mar 2021'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '23 Mar 2021'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '25 Mar 2021'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:57:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:57:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	06 Apr 2021 19:34:58
	(b) (4)	

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample with a Collection date of 02NOV2020, however this sample is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 12:20:53
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample with a Collection date of 02NOV2020, however this sample is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' answered with 'per ePIP, advised to enter as an illness visit.' (Site from DM).	Andrea Wendrow (b) (4)	12 Dec 2020 18:16:47
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample with a Collection date of 02NOV2020, however this sample is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:15:01
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:36:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:36:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[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 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Clinic (Clinic)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:36:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'SICKD1'	System	14 Nov 2020 20:36:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '10:27'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered '2 Nov 2020 10:27'	System	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14
DataPoint set to visible.	(b) (4) System	14 Nov 2020 20:36:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14
DataPoint set to visible.	(b) (4) System	14 Nov 2020 20:36:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '97.4' F	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (Other)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'ear'	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '63'	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'bpm'	System	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '12'	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'breaths/min'	System	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '102'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'mmHg'	System	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '69'	Andrea Wendrow (b) (4)	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'mmHg'	System	14 Nov 2020 20:38:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:38:55

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

[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 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:42:56

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 02 NOV 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 09:05:15
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 02 NOV 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab. ' answered with 'PLEASE read the previous query comments. It HAS been reported.' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	16 Feb 2021 16:20:05
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 02 NOV 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:16:31

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 02 NOV 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 13:34:34
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 02 NOV 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'it's already been reported. Accession number 1F60GWD. It is showing in Preclarus as Visit 3 Month 2 as subject came in for visit and bloods were drawn for visit and it was then determined that it should have been an illness visit. NP swab collected same day with an unscheduled visit kit.' (Site from DM).	Andrea Wendrow (b) (4)	14 Jan 2021 16:42:38
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 02 NOV 2020 SARS-CoV-2 serum sample reported under illness Visit Day 1, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:26:55
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:29:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

2240 of 3295

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'It is 1F602667048 and it shows in Preclarus as shipped from site' (Site from DM).	Andrea Wendrow (b) (4)	(b) (4) 04 Dec 2020 19:30:52
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:53:58
User entered '2 Nov 2020'	Andrea Wendrow (b) (4)	(b) (4) 14 Nov 2020 20:42:56

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21,23,25MAR2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:10:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21,23,25MAR2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	06 Apr 2021 19:36:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21,23,25MAR2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:46:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[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 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'SICKD1'	System	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '11:50'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered '19 Mar 2021 11:50'	System	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42
DataPoint set to visible.	System	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42
DataPoint set to visible.	System	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '79'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'bpm'	System	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'breaths/min'	System	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '116'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'mmHg'	System	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '74'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User entered 'mmHg'	System	19 Mar 2021 17:13:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:47

US3492085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:47

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

[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 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:54

US3492085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 07:57:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:14
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:13:54

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	19 Mar 2021 17:12:42

US3492085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	19 Mar 2021 17:12:42

US3492085

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

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:24:06

US3492085

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

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:24:06

US3492085

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

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:24:06

US3492085

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

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 19:24:06

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:49:03

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:49:03

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '1'	System	01 Feb 2021 19:25:00

US3492085

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

Form: Unblinding

Generated On: 10 Jun 2021 07:57:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'I'	System	01 Feb 2021 19:25:00

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	04 Feb 2021 18:46:25
DataPoint set to visible.	System	01 Feb 2021 19:25:00

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	04 Feb 2021 18:46:25
DataPoint set to visible.	System	01 Feb 2021 19:25:00

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '13:33'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '01 Feb 2021 13:33'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '70'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'bpm'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '14'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'breaths/min'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '106'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'mmHg'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '65'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'mmHg'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	04 Feb 2021 18:46:25
DataPoint set to visible.	System	01 Feb 2021 19:25:00

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '14:46'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '01 Feb 2021 14:46'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'ear'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '62'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'bpm'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '14'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'breaths/min'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '112'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'mmHg'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '72'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:46:25

US3492085

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'mmHg'	System	04 Feb 2021 18:46:25

US3492085

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

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:40:32

US3492085

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

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:40:32

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:21

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:21

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:21

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:21

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM query : FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 10:12:49
Query 'Per CDM query : FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	05 Feb 2021 21:12:44
User opened query 'Per CDM query : FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:54:30
User entered 'No (N)'	(b) (4), (b) (6)	01 Feb 2021 21:08:21

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4)	05 Feb 2021 21:12:36
User entered '1 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 21:08:21

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4)	05 Feb 2021 21:12:36
User entered '13:33'	Marla Schwarber (b) (4)	01 Feb 2021 21:08:21
	(b) (4), (b) (6)	

US3492085

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered empty.	System	05 Feb 2021 21:12:36
User entered '1 Feb 2021 13:33'	System	01 Feb 2021 21:08:21

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'mRNA-1273'	System	01 Feb 2021 21:08:33
DataPoint set to visible.	System	01 Feb 2021 19:25:00

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '14:06'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '1 Feb 2021 14:06'	System	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'ONCE'	System	01 Feb 2021 21:08:33

US3492085

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

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 21:08:33

US3492085

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:07

US3492085

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:07

US3492085

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '13:12'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:07

US3492085

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '1 Feb 2021 13:12'	System	01 Feb 2021 19:25:07

US3492085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:15

US3492085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:57:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:15

US3492085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:57:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '13:17'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:25:15

US3492085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered '1 Feb 2021 13:17'	System	01 Feb 2021 19:25:15

US3492085

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

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:08:38

US3492085

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

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:02:41
User entered 'I'	System	01 Feb 2021 21:08:38

US3492085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	08 Feb 2021 14:41:25

US3492085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '8 Feb 2021'	Nia Moragne-O'Neal (b) (4)	08 Feb 2021 14:41:25

US3492085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	08 Feb 2021 14:41:25

US3492085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Nia Moragne-O'Neal (b) (4)	08 Feb 2021 14:41:25

US3492085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	08 Feb 2021 14:41:29

US3492085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'I'	System	08 Feb 2021 14:41:29

US3492085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered '1'	System	08 Feb 2021 14:41:29
DataPoint set to visible.	System	08 Feb 2021 14:41:29

US3492085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:42:05

US3492085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:42:05

US3492085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:42:05

US3492085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'OLD29'	System	01 Mar 2021 20:42:05

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '12:54'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered '1 Mar 2021 12:54'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '71'	(b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'bpm'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '15'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'breaths/min'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '104'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'mmHg'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '68'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'mmHg'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '14:36'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered '1 Mar 2021 14:36'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'tympenic'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '71'	(b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'bpm'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'breaths/min'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '107'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'mmHg'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '69'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'mmHg'	System	01 Mar 2021 20:44:20

US3492085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:36

US3492085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:44:36

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '13:18'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered empty.	System	01 Mar 2021 20:45:39

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'mRNA-1273'	System	01 Mar 2021 20:46:18
DataPoint set to visible.	System	08 Feb 2021 14:41:29

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '14:04'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered '1 Mar 2021 14:04'	System	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'ONCE'	System	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 20:46:18

US3492085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:46:25

US3492085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'I'	System	01 Mar 2021 20:46:25

US3492085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:19:33

US3492085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:19:33

US3492085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:19:33

US3492085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:19:33

US3492085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:19:42

US3492085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:57
User entered 'I'	System	09 Mar 2021 19:19:42

US3492085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:08

US3492085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:08

US3492085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:08

US3492085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:38:08

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '13:05'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:05'	System	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '61'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '17'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '97'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '62'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:38:52

US3492085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:59

US3492085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:38:59

US3492085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:39:22

US3492085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: GCL has Immunogenicity sample date 02NOV2020 for Illness visit Day1 which is not recorded in EDC. Please confirm if for Illness visit, Immuno sample was also collected with SARS COV2 sample then the data for Immunogenicity sample will be updated under UNSCHEDULED visit as Illness visit does not have form to record Immunogenicity sample.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:13:51
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: GCL has Immunogenicity sample date 02NOV2020 for Illness visit Day1 which is not recorded in EDC. Please confirm if for Illness visit, Immuno sample was also collected with SARS COV2 sample then the data for Immunogenicity sample will be updated under UNSCHEDULED visit as Illness visit does not have form to record Immunogenicity sample.' answered with 'why is this under OL D57?' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	09 Apr 2021 21:59:38
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: GCL has Immunogenicity sample date 02NOV2020 for Illness visit Day1 which is not recorded in EDC. Please confirm if for Illness visit, Immuno sample was also collected with SARS COV2 sample then the data for Immunogenicity sample will be updated under UNSCHEDULED visit as Illness visit does not have form to record Immunogenicity sample.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:18:03
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:39:22

US3492085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '13:08'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:39:22

US3492085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 13:08'	System	30 Mar 2021 18:39:22

US3492085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:57:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:10
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:06:24
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'added to adverse events' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:06:40
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:57
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:06:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Elena Llinas (b) (4)	22 Sep 2020 20:04:44
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 14:11:08

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MUSCLE SORENESS. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:58:57
User closed query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:58:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 23:26:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 23:26:38
Data point term sent to Coder	System	11 Nov 2020 03:24:44
Query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MUSCLE SORENESS. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:24:15
Coding entries removed.	Andrea Wendrow (b) (4)	11 Nov 2020 03:24:04
User entered 'MUSCLE SORENESS FROM EXERCISING-generalized' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	11 Nov 2020 03:24:04

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	Andrea Wendrow (b) (4)	11 Nov 2020 03:23:36
answered with 'not COVID related' (Site from DM). User opened query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).'	(b) (4), (b) (6)	05 Nov 2020 10:18:16
(Site from DM). User opened query 'Per DM CLR: Please specify the location (e.g., Generalized, Right Arm, Both Legs, etc) of MUSCLE SORENESS. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.'	(b) (4), (b) (6)	23 Oct 2020 01:14:31
(Site from DM). User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle soreness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:34:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:34:34
Data point term sent to Coder	System	22 Sep 2020 20:08:08
User entered 'muscle soreness from exercising'	Elena Llinas (b) (4) (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '20 Sep 2020'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
User entered empty.	System	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '22 Sep 2020'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
User entered empty.	System	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:22:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 21:22:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Addis Mekonnen (b) (4)	22 Sep 2020 21:22:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:07:36
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 21:22:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 21:22:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Addis Mekonnen (b) (4)	22 Sep 2020 21:22:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:07:36
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:08:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:08:11
User entered 'None (NONE)' reason for change: Data Entry Error	Elena Llinas (b) (4)	22 Sep 2020 20:08:11
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:07:36
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
Signature has been broken.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	22 Sep 2020 21:22:38
User entered '0' reason for change: Data Entry Error	Addis Mekonnen (b) (4)	22 Sep 2020 21:22:38
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	22 Sep 2020 20:07:36
User entered '1'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
Signature has been broken.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:30:46
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Ibuprofen listed in concomitant medication ' (Site from DM).	Marla Schwarber (b) (4)	20 Oct 2020 19:47:08
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:58:57
User entered 'I'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Subject exercised and got muscle soreness. She took some Ibuprofen.'	Elena Llinas (b) (4)	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
User entered '0'	System	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17
User entered '0'	System	22 Sep 2020 20:07:36

US3492085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:17

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 20:06:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 20:06:51
Data point term sent to Coder	System	14 Nov 2020 20:05:58
Coding entries removed.	Andrea Wendrow (b) (4)	14 Nov 2020 20:05:06
User entered 'strep throat' reason for change: New Information	(b) (4)	
User closed query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	Andrea Wendrow (b) (4)	14 Nov 2020 20:05:06
Query 'Per MM, please confirm if the subject was evaluated for COVID-19' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:59:17
User opened query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:28:17
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.	(b) (4), (b) (6)	05 Nov 2020 10:21:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:19:34
Data point term sent to Coder	Coder Import (b) (4)	29 Sep 2020 19:19:34
User entered 'Upper Respiratory Infection'	System	29 Sep 2020 19:18:16
	Elena Llinas (b) (4)	29 Sep 2020 19:18:06
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:59:18
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'data entry error corrected' (Site from DM).	Andrea Wendrow (b) (4)	11 Nov 2020 03:28:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 03:27:38
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 05:30:32
User entered 'Yes (Y)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '24 Sep 2020'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
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	29 Sep 2020 19:18:36
User entered empty; reason for change Data Entry Error	Elena Llinas (b) (4)	29 Sep 2020 19:18:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 19:18:22
User entered '20:00' reason for change: Data Entry Error	Elena Llinas (b) (4)	29 Sep 2020 19:18:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 19:18:06
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	29 Sep 2020 19:18:06
User entered '20:' (non-conformant).	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
User entered empty.	System	29 Sep 2020 19:18:36
User entered '24 Sep 2020 20:00'	System	29 Sep 2020 19:18:22
User entered '24 Sep 2020 20:' (non-conformant).	System	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '25 Oct 2020' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	31 Dec 2020 17:49:22
User entered '09 Oct 2020' reason for change: New Information	Andrea Wendrow (b) (4)	14 Nov 2020 20:05:06
User entered '28 Sep 2020'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
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	29 Sep 2020 19:18:50
User entered empty; reason for change Data Entry Error	Elena Llinas (b) (4)	29 Sep 2020 19:18:50
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	29 Sep 2020 19:18:06
User entered '12:00'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
User entered empty.	System	29 Sep 2020 19:18:50
User entered '28 Sep 2020 12:00'	System	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Wendrow (b) (4)	31 Dec 2020 17:49:22
reason for change: Per Query Resolution	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'None (NONE)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query ' Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:09:24
Query ' Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 20:05:16
User opened query ' Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:33:44
User entered 'I'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'WENT TO MIDWEST HEALTH CLINIC AND WAS PRESCRIBED AMOXICILLIN AND LIDOCAINE MOUTHWASH PARTICIPANT IS TAKING AUGMENTIN. PER SAFETY CALL DAYS 36 AND 43, RECEIVED 3 MORE COURSES OF ANTIBIOTICS, IS CURRENTLY COMPLETING AND IS FEELING BETTER, NOT COMPLETELY RESOLVED YET. EVENT COMPLETELY RESOLVED AS OF 25OCT2020.' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	31 Dec 2020 17:49:22
User entered 'Went to Midwest Health Clinic and was prescribed Amoxicillin and Lidocaine mouthwash'	Elena Llinas (b) (4)	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
User entered '0'	System	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22
User entered '1'	System	29 Sep 2020 19:18:06

US3492085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:22

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia worsened - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:55:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:55:56
Data point term sent to Coder	System	05 Oct 2020 17:55:55
User entered 'fibromyalgia flare'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 17:55:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 17:55:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:55:46
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 17:55:36
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '24 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
User entered empty.	System	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '28 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
User entered empty.	System	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:31
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 03:31:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4) (b) (4)	11 Nov 2020 03:31:21
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 05:30:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	05 Oct 2020 17:55:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 17:55:46
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Oct 2020 17:55:36
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: SAE Narrative = HAS MUSCLE RELAXERS. Please confirm if this was given. If yes, please ensure that this is recorded on the CM eCRF and indication is verbatim to the AE term so there will be an appropriate match. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:10:15
Query 'Per DM CLR: SAE Narrative = HAS MUSCLE RELAXERS. Please confirm if this was given. If yes, please ensure that this is recorded on the CM eCRF and indication is verbatim to the AE term so there will be an appropriate match. Review and update eCRF as appropriate. ' answered with 'updated narrative and con med log' (Site from DM).	Andrea Wendrow (b) (4)	14 Nov 2020 20:22:21
User entered 'PARTICIPANT IS MONITORING AND HAS MUSCLE RELAXERS. Uses methocarbamol to treat the fibromyalgia' reason for change: New Information	Andrea Wendrow (b) (4)	14 Nov 2020 20:21:50
User opened query 'Per DM CLR: SAE Narrative = HAS MUSCLE RELAXERS. Please confirm if this was given. If yes, please ensure that this is recorded on the CM eCRF and indication is verbatim to the AE term so there will be an appropriate match. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:33:56
User entered 'participant is monitoring and has muscle relaxers'	(b) (4), (b) (6)	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
User entered '0'	System	05 Oct 2020 17:55:36

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27
User entered '0'	System	05 Oct 2020 17:55:46

US3492085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:27

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:26:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:26:40
Data point term sent to Coder	System	21 Oct 2020 19:25:58
User entered 'diarrhea'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '11 Oct 2020'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
User entered empty.	System	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	Michelle Agnoli (b) (4)	30 Oct 2020 20:10:52
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:11:21
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	30 Oct 2020 20:11:21
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:11:21
User entered '24 Oct 2020' reason for change: New Information	Michelle Agnoli (b) (4)	30 Oct 2020 20:11:21
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:10:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:10:52
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
User entered empty.	System	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'None (NONE)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'l'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Michelle Agnoli (b) (4)	30 Oct 2020 20:10:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Lorna Sanchez McCann (b) (4)	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Diarrhea resolved 24OCT2020.'	(b) (4)	
reason for change: New Information	Michelle Agnoli (b) (4)	30 Oct 2020 20:10:52
User entered empty.	(b) (4)	
	Lorna Sanchez McCann	21 Oct 2020 19:25:29
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
User entered '0'	System	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32
User entered '0'	System	21 Oct 2020 19:25:29

US3492085

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:32

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:29
User entered 'USA-US101-2020-mRNA-1273-P301000009'	System	04 Dec 2020 14:22:18
User entered 'New'	(b) (4), (b) (6)	04 Dec 2020 14:22:18

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:53:50
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:47:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 18:47:50
Data point term sent to Coder	System	10 Feb 2021 18:46:49
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 18:46:21
Coding entries removed.	(b) (4), (b) (6)	10 Feb 2021 18:46:13
User entered 'benign RIGHT OVARIAN CYST' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Feb 2021 18:46:13
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:54:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 15:53:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 15:53:29
Data point term sent to Coder	System	03 Dec 2020 15:52:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

2600 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'RIGHT OVARIAN CYST'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:51:45
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '26 Nov 2020'	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:51:45
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	31 Dec 2020 17:42:58
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '25 Dec 2020' reason for change: Data Entry Error	(b) (4)	31 Dec 2020 17:42:58
User entered empty.	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'provided' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	31 Dec 2020 17:43:20
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	14 Dec 2020 14:02:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 14:02:05
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	14 Dec 2020 14:01:40
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 14:01:40
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:04:40
User entered empty.	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Grade 4 (Grade 4)'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	03 Dec 2020 15:53:52
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	03 Dec 2020 15:53:52
User entered 'Yes (Y)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:53:52
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 15:51:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 15:51:55
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	03 Dec 2020 15:51:55
User entered 'No (N)' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:55
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 15:51:45
User entered empty.	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:51:45
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1' reason for change: Per Query Resolution	(b) (4)	03 Dec 2020 15:53:52
User entered '0'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	03 Dec 2020 15:51:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Dec 2020 15:51:45
User entered '0'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'PV Query: Please provide any additional 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 additional treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:44
Query 'PV Query: Please provide any additional 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 additional treatment was provided, please state so.' answered with 'in eCRF' (Site from Safety).	Andrea Wendrow (b) (4)	31 Dec 2020 17:43:43
User opened query 'PV Query: Please provide any additional 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 additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:04:10
User entered '1' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:55
User entered '0'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1' reason for change: New Information	(b) (4), (b) (6)	10 Feb 2021 18:39:09
User entered '0'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 21:07:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' answered with 'provided' (Site from Safety).	Andrea Wendrow (b) (4)	31 Dec 2020 17:43:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andrea Wendrow (b) (4)	31 Dec 2020 17:42:58
New Information		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 22:05:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User closed query 'PV Query: Please confirm if right lower quadrant pain is a symptom of right ovarian cyst.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:34:15
Query 'PV Query: Please confirm if right lower quadrant pain is a symptom of right ovarian cyst.' answered with 'Confirmed. participant got checked out for right lower quadrant pain then was diagnosed with a right ovarian cyst' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 13:54:43
User opened query 'PV Query: Please confirm if right lower quadrant pain is a symptom of right ovarian cyst.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 14:30:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Narrative indicates that subject had "RIGHT LOWER QUADRANT PAIN and ULTRASOUND." However, these are not recorded in the AE and Concomitant Procedure eCRFs respectively. Review and record these as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:55:02
Query 'Per DM CLR: Narrative indicates that subject had "RIGHT LOWER QUADRANT PAIN and ULTRASOUND." However, these are not recorded in the AE and Concomitant Procedure eCRFs respectively. Review and record these as appropriate. Otherwise, clarify.' answered with 'added right lower quadrant pain to AE and ultrasound to con procedures' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 18:43:51
User closed query 'PV Query: Thank you for requesting the gynecological consult note. Please provide this information once it becomes available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:17:00
User opened query 'Per DM CLR: Narrative indicates that subject had "RIGHT LOWER QUADRANT PAIN and ULTRASOUND." However, these are not recorded in the AE and Concomitant Procedure eCRFs respectively. Review and record these as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:54:53

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PPT WENT TO EMERGENCY ROOM DUE TO RIGHT LOWER QUADRANT PAIN. SHE WAS DIAGNOSED WITH RIGHT OVARIAN CYST AFTER UNDERGOING AN ULTRASOUND. PPT WAS DISCHARGED TO HOME WITH A PRESCRIPTION FOR HYDROCODONE. PPT WILL FOLLOW UP WITH GYNECOLOGIST 09DEC2020. PPT IS RESTING AT HOME AND DENIES ANY OTHER SYMPTOMS. CYST WAS SURGICALLY REMOVED DECEMBER 10, pathology was negative, SEE PROCEDURE LOG' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 19:04:29
Query 'PV Query: Thank you for requesting the gynecological consult note. Please provide this information once it becomes available. Please leave query open until information is received.' answered with 'updated, see procedure log, pathology was negative' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 19:03:43
User entered 'PPT WENT TO EMERGENCY ROOM DUE TO RIGHT LOWER QUADRANT PAIN. SHE WAS DIAGNOSED WITH RIGHT OVARIAN CYST AFTER UNDERGOING AN ULTRASOUND. PPT WAS DISCHARGED TO HOME WITH A PRESCRIPTION FOR HYDROCODONE. PPT WILL FOLLOW UP WITH GYNECOLOGIST 09DEC2020. PPT IS RESTING AT HOME AND DENIES ANY OTHER SYMPTOMS. CYST WAS SURGICALLY REMOVED December 10, SEE PROCEDURE LOG' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 19:03:24

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PPT WENT TO EMERGENCY ROOM DUE TO RIGHT LOWER QUADRANT PAIN. SHE WAS DIAGNOSED WITH RIGHT OVARIAN CYST AFTER UNDERGOING AN ULTRASOUND. PPT WAS DISCHARGED TO HOME WITH A PRESCRIPTION FOR HYDROCODONE. PPT WILL FOLLOW UP WITH GYNECOLOGIST 09DEC2020. PPT IS RESTING AT HOME AND DENIES ANY OTHER SYMPTOMS. CYST WAS SURGICALLY REMOVED DECEMEER 10, SEE PROCEDURE LOG' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 19:03:07
User entered 'PPT WENT TO EMERGENCY ROOM DUE TO RIGHT LOWER QUADRANT PAIN. SHE WAS DIAGNOSED WITH RIGHT OVARIAN CYST AFTER UNDERGOING AN ULTRASOUND. PPT WAS DISCHARGED TO HOME WITH A PRESCRIPTION FOR HYDROCODONE. PPT WILL FOLLOW UP WITH GYNECOLOGIST 09DEC2020. PPT IS RESTING AT HOME AND DENIES ANY OTHER SYMPTOMS.	(b) (4), (b) (6)	01 Feb 2021 19:02:55
Cyst was surgically removed decemeber 10, see procedure log' reason for change: Data Entry Error		
User opened query 'PV Query: Thank you for requesting the gynecological consult note. Please provide this information once it becomes available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:51:48
User closed query 'PV Query: Please provide a gynecological consult note when available. ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 21:07:38
Query 'PV Query: Please provide a gynecological consult note when available. ' answered with 'requested' (Site from Safety).	Andrea Wendrow (b) (4)	31 Dec 2020 17:44:17
User opened query 'PV Query: Please provide a gynecological consult note when available. ' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 23:52:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Dec 2020 15:56:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

2634 of 3295

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Dec 2020 15:56:32
User entered 'ppt WENT TO eMERGENCY rOOM due to right lower quadrant pain. she was diagnosed with right ovarian cyst after undergoing an ultrasound. ppt was discharged to home with a prescription for hydrocodone. ppt will follow up with gynecologist 09dec2020. ppt is resting at home and denies any other symptoms.' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:56:32
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Dec 2020 15:53:52
User entered empty.	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Dec 2020 15:53:52
User entered '0'	System	03 Dec 2020 15:51:55

US3492085

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Dec 2020 15:51:45

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:44:53
User entered 'USA-US101-2020-mRNA-1273-P301000009'	(b) (4), (b) (6)	11 Feb 2021 18:44:21

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 18:37:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Feb 2021 18:37:51
Data point term sent to Coder	System	10 Feb 2021 18:37:38
User entered 'Right lower quadrant pain'	(b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	10 Feb 2021 18:43:16
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 18:40:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 18:40:07
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 18:38:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 18:38:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 18:38:05
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 18:37:34
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:43:16
User entered '0'	(b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	10 Feb 2021 18:40:07
reason for change: Data Entry Error		
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 11:14:33
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:49:45
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 13:49:40
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 13:49:40
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:44:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'participant went to the ER for right lower quadrant pain and was diagnosed with an ovarian cyst. see ovarian cyst AE and procedures log for more information'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 18:40:07
User entered '0'	System	10 Feb 2021 18:38:05

US3492085

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 18:37:34

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 18:22:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 18:22:06
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 18:21:28
Coding entries removed.	Andrea Wendrow (b) (4)	30 Mar 2021 18:21:22
	(b) (4)	
User entered 'Tonsilitis' reason for change: New Information	Andrea Wendrow (b) (4)	30 Mar 2021 18:21:22
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 21:58:29
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 14:20:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 14:20:33
	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 14:20:05
User entered 'Sore throat'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:21:22
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '14 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42
User entered empty.	System	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42
User entered empty.	System	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:21:22
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 11:58:03
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:51:22
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:15
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 12:51:15
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 15:48:20
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '1'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 12:51:15
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 12:51:15
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:21:22
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:55:04
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4) (b) (4)	19 Mar 2021 21:57:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42
User entered '0'	System	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:21:22
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42
User entered 'O'	System	19 Mar 2021 14:19:11

US3492085

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	30 Mar 2021 18:20:34
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	19 Mar 2021 21:57:42

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 18:14:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 18:14:23
	(b) (4)	
Data point term sent to Coder	System	29 Mar 2021 18:13:18
User entered 'Muscles Aches'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' answered with 'Symptom lasted beyond Day 7.. Per FAQ v26.0_26Mar2021.pdf page 31 of 119 it is to be reported as an UNSOLICITED AE' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:57:38
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = NO. However, this was also captured on the subject's Diary record on these dates. Please review and update response to YES as appropriate. Otherwise, clarify.' (Site from DM).	Marla Schwarber (b) (4)	06 Apr 2021 18:30:20
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 15:48:45
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 14:06:27
User entered '11 Oct 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Apr 2021 14:06:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '12 Oct 2020'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User entered empty.	System	29 Mar 2021 18:13:15

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '13 Oct 2020'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User entered empty.	System	29 Mar 2021 18:13:15

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'No (N)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Related (RELATED)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'l'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered '0'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:55:04
User entered empty.	Andrea Wendrow (b) (4)	29 Mar 2021 18:13:15
	(b) (4)	

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User entered '0'	System	29 Mar 2021 18:13:15

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38
User entered '0'	System	29 Mar 2021 18:13:15

US3492085

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:47:38

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 22:09:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 22:09:24
Data point term sent to Coder	System	03 May 2021 22:08:30
User entered 'Right Lower Quadrant Pain'	(b) (4), (b) (6) (b) (4)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Apr 2021'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:08:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 22:08:12
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 22:08:12
User opened query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 22:08:04
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[None](#)

Audit	User	Time (GMT)
User entered 'l'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 22:08:04

US3492085

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 07:57:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 22:08:04

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:57:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:24:55

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:02:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:02:40
Data point term sent to Coder	System	10 Sep 2020 14:01:33
User entered 'loratadine'	(b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'seasonal allergies'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'daily, as needed'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:00:44

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:03:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:03:37
Data point term sent to Coder	System	10 Sep 2020 14:02:34
User entered 'albuterol mdi'	(b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mild asthma'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'every 6 hours as needed'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:01:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:05:47
Data point term sent to Coder	System	10 Sep 2020 14:04:36
User entered 'pepcid'	(b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:03:47

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE, PRODUCTSYNONYM: TRUVADA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:05:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 14:05:46
Data point term sent to Coder	System	10 Sep 2020 14:04:36
User entered 'truvada'	(b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'PREP'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:23:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un Oct 2020' reason for change: New Information	(b) (4)	14 Nov 2020 20:23:24
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User entered '1'	System	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User entered '1'	System	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:01:13
User entered '804 (804)'	System	10 Sep 2020 14:04:20

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:06:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:06:51
Data point term sent to Coder	System	10 Sep 2020 14:05:40
User entered 'biotin'	(b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'general health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:04:51

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
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: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:06:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:06:50
Data point term sent to Coder	System	10 Sep 2020 14:05:39
User entered 'vitamin d'	(b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'general health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 14:05:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 14:07:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:07:36
Data point term sent to Coder	System	10 Sep 2020 14:06:44
User entered 'multivitamin'	(b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'general health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Unknown is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:07:00
Query 'Per CDM: Unknown is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:00:03
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:59:57
User opened query 'Per CDM: Unknown is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:38:02
User entered 'other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:59:57
User entered 'not specified'	(b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:06:10

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 19:44:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 19:44:51
Data point term sent to Coder Coding entries removed.	System Andrea Wendrow (b) (4)	14 Nov 2020 19:43:54 14 Nov 2020 19:43:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:37:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 15:37:30
Data point term sent to Coder User entered 'methocarbamol'	System (b) (4), (b) (6)	10 Sep 2020 14:07:44 10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:12:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 19:45:36
User entered 'Fibromyalgia' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 19:43:26
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:33:57
User entered 'muscle relaxant'	(b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 10:49:56
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated, participant does not know' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 19:02:10
User entered 'unk' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 19:02:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:44:21
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 19:02:01
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'unk' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 19:02:01
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:07:08

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 08:56:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 08:56:17
Data point term sent to Coder	System	30 Oct 2020 16:17:51
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 16:17:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 16:43:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 16:43:35
Data point term sent to Coder	System	17 Sep 2020 16:42:42
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	17 Sep 2020 16:42:08
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated, changed spelling' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 16:42:08
User entered 'Mirena IUD' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:41:57

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	16 Sep 2020 05:22:48
Data point term sent to Coder	System	10 Sep 2020 14:11:49
User entered 'meridian iud'	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'contraception'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:07:17
Query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:01:10
User entered 'unk' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:00:59
User opened query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:58:44
User entered 'na'	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'unk' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:00:59
User entered 'na'	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per CDM: Unknown is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:07:11
Query 'Per CDM: Unknown is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:01:16
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:00:59
User opened query 'Per CDM: Unknown is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:38:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 15:00:59
User entered 'na'	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 13:52:34
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:17:08
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:17:03
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:34:51
User entered 'Vaginal (VAGINAL)'	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'uterine' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Oct 2020 16:17:03
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:10:53

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:43:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:43:40
Data point term sent to Coder	System	14 Nov 2020 20:08:58
Data point term sent to Coder	System	14 Nov 2020 19:49:56
Coding entries removed.	Andrea Wendrow (b) (4)	14 Nov 2020 19:49:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 19:50:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 19:50:43
Data point term sent to Coder	System	22 Sep 2020 19:49:44
User entered 'Ibuprofen'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:12:25
User entered 'generalized muscle soreness from exercising' reason for change: New Information	Andrea Wendrow (b) (4)	14 Nov 2020 20:08:19
Query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'done' (Site from DM).	Andrea Wendrow (b) (4)	14 Nov 2020 19:49:57
User entered 'fibromyalgia related pain' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	14 Nov 2020 19:49:50
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:03:03
User entered 'pain relief'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '600'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mg (mg)'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'as needed (PRN)'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '20 Sep 2020' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:08:19
User entered empty.	(b) (4) Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0' reason for change: New Information	(b) (4)	
	Andrea Wendrow (b) (4)	14 Nov 2020 20:08:19
User entered '1'	(b) (4)	
	Elena Llinas (b) (4)	22 Sep 2020 19:49:30
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	14 Nov 2020 20:08:19
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:49:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:49:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Elena Llinas (b) (4)	22 Sep 2020 19:49:41
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 19:49:30
User entered empty.	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	14 Nov 2020 20:08:19
User entered empty.	(b) (4)	
	Elena Llinas (b) (4)	22 Sep 2020 19:49:30
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User entered empty.	System	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User entered empty.	System	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:15
User entered empty.	System	22 Sep 2020 19:49:30

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 08:14:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 08:14:38
Data point term sent to Coder	System	29 Sep 2020 19:23:28
User entered 'Lidocaine mouthwash'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'pain relief of sore throat'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '15'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mL (mL)'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'as needed (PRN)'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Topical (TOPICAL)'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '26 Sep 2020'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '28 Sep 2020'	Elena Llinas (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:38:41
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:06:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 16:06:41
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 07:46:35
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User entered empty.	System	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User entered empty.	System	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:19
User entered empty.	System	29 Sep 2020 19:23:18

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 14:40:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 14:40:57
Data point term sent to Coder	System	24 Feb 2021 14:40:04
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 14:39:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:21:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 17:21:42
Data point term sent to Coder	System	08 Dec 2020 16:08:50
Coding entries removed.	(b) (4), (b) (6)	08 Dec 2020 16:08:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 20:29:52
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 Nov 2020 20:29:52
Data point term sent to Coder	System	14 Nov 2020 20:29:03

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
Data point term sent to Coder	System	21 Oct 2020 19:55:07
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 19:26:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 19:26:53
Data point term sent to Coder	System	29 Sep 2020 19:25:32
User entered 'Amoxicillin'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'No (N)'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 13:05:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'changed to match AE' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 14:39:34
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 14:39:27
User entered 'strep throat' reason for change: New Information	(b) (4), (b) (6)	24 Feb 2021 14:39:27
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:57:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:39:24
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:10:47
User entered 'ANTIBIOTIC for upper respiratory infection' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 16:08:26

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 12:54:48
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'antibiotic'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered '500'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'mg (mg)'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'twice daily (BID)'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered empty.	(b) (4)	
	Elena Llinas (b) (4)	29 Sep 2020 19:25:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'Oral (ORAL)'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered '26 Sep 2020'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered '0'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 05:42:11
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:48:11
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:48:06
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	31 Mar 2021 19:48:06
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 06:58:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	(b) (4) Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User entered '02 Oct 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	31 Mar 2021 19:49:16
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:48:06
User entered '09 Oct 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	31 Mar 2021 19:48:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered empty.	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:39:49
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:11:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 16:10:42
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 12:55:13
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered 'Yes (Y)'	Elena Llinas (b) (4)	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered '2'	System	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered '1'	System	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:23
DataPoint activated with code reason code Data required.	Andrea Wendrow (b) (4)	14 Nov 2020 20:28:52
DataPoint inactivated with code reason code Data not required.	Andrea Wendrow (b) (4)	21 Oct 2020 19:54:39
User entered '804 (804)'	System	29 Sep 2020 19:25:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 16:58:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 16:58:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:53:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:53:20
Data point term sent to Coder	System	05 Oct 2020 17:52:44
User entered 'augmentin'	(b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'strep throat'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 01:49:05
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'dosage updated' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 16:52:10
User entered '875 / 125' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 16:51:56
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 04:28:48
User entered '875'	(b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	12 Oct 2020 15:21:04
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:21:04
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Oct 2020 15:20:56
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	12 Oct 2020 15:20:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:20:56
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	05 Oct 2020 17:52:14
User entered '09 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User entered '2'	System	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User entered '1'	System	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:30
User entered '804 (804)'	System	05 Oct 2020 17:52:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:13:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:13:34
Data point term sent to Coder	System	14 Oct 2020 16:02:36
User entered 'Clindamycin'	Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'strep throat'	(b) (4) Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '300'	Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mg (mg)'	(b) (4) Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'three times daily (TID)'	(b) (4) Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '12 Oct 2020'	(b) (4) Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	21 Oct 2020 19:57:52
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	21 Oct 2020 19:57:52
User entered empty.	(b) (4)	
	Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	21 Oct 2020 19:57:52
User entered 'Yes (Y)'	Lorna Sanchez McCann	14 Oct 2020 16:02:19
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User entered '3'	System	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User entered '1'	System	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:49
User entered '804 (804)'	System	14 Oct 2020 16:02:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 04:54:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 04:54:24
Data point term sent to Coder	System	21 Oct 2020 20:01:32
User entered 'Vancomycin'	Andrea Wendrow (b) (4) (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
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	21 Oct 2020 20:00:59
User entered 'No (N)' reason for change: Data Entry Error	System	21 Oct 2020 20:00:59
User opened query 'Data is required. Please complete.' (Site from System).	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:59
User entered empty.	(b) (4)	
	System	21 Oct 2020 20:00:42
	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Strep throat'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '125'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mg (mg)'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'four times daily (QID)'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '17 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	14 Nov 2020 20:32:40
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Wendrow (b) (4)	14 Nov 2020 20:32:40
User entered empty.	(b) (4)	
	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Andrea Wendrow (b) (4)	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User entered '4'	System	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User entered '1'	System	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:56
User entered '804 (804)'	System	21 Oct 2020 20:00:42

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 20:35:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 20:35:52
Data point term sent to Coder	System	14 Nov 2020 20:35:04
User entered 'influenza vaccine'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'influenza prevention'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0.5'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mL (mL)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'once (ONCE)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '27 Oct 2020'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '27 Oct 2020'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Andrea Wendrow (b) (4)	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	14 Nov 2020 20:34:19

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 22:55:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 22:55:08
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	24 Feb 2021 14:34:59 24 Feb 2021 14:34:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 17:21:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 17:21:44
Data point term sent to Coder Coding entries removed.	System Gizelle Alvarez (b) (4) (b) (4)	01 Dec 2020 18:04:28 01 Dec 2020 18:04:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 17:56:50

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	01 Dec 2020 17:56:50
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	01 Dec 2020 17:56:19
User entered 'IBUPROFEN'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 13:06:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated to match AE' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 14:35:06
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 14:34:57
User entered 'benign right ovarian cyst pain' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 14:34:57
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:59:17
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Note, there is a medical condition if RIGHT OVARIAN CYST. Please confirm if this Con Med is given for this AE. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. Thankyou.' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:04:14

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Note, there is a medical condition if RIGHT OVARIAN CYST. Please confirm if this Con Med is given for this AE. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Otherwise, add a medical condition and all applicable details to the appropriate AE eCRF. Thankyou.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	15 Feb 2021 11:04:00
User entered 'Right lower quadrant abdominal PAIN' reason for change: Data Entry Error User entered 'PAIN'	Richard Novak (b) (4) (b) (4) Gizelle Alvarez (b) (4) (b) (4) Gizelle Alvarez (b) (4) (b) (4)	15 Feb 2021 03:39:54 01 Dec 2020 18:04:11 01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '800'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'mg (mg)'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'as needed (PRN)'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '28 Nov 2020'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	31 Dec 2020 17:36:40
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '25 Dec 2020' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	31 Dec 2020 17:36:40
User entered empty.	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	Gizelle Alvarez (b) (4)	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:06
User entered empty.	System	01 Dec 2020 17:55:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 06:44:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 06:44:07
Data point term sent to Coder	System	24 Feb 2021 14:37:01
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 14:36:12
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 14:36:12
User entered 'HYDROCODONE/acetaminophen 5/325' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 14:36:12
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:11:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:11:58
Data point term sent to Coder	System	03 Dec 2020 15:58:23
User entered 'hydrocodone 5/325'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'right ovarian cyst pain'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User closed query 'Per DM CLR: Please review recorded dose in medication name as Hydrocortisone is single component medication. Either provide the other component (eg, acetaminophen) or update dose to a single component dose in the dose and dose unit field. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:31:17
Query 'Per DM CLR: Please review recorded dose in medication name as Hydrocortisone is single component medication. Either provide the other component (eg, acetaminophen) or update dose to a single component dose in the dose and dose unit field. Update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 14:36:16
User opened query 'Per DM CLR: Please review recorded dose in medication name as Hydrocortisone is single component medication. Either provide the other component (eg, acetaminophen) or update dose to a single component dose in the dose and dose unit field. Update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 23:00:22
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '2'	(b) (4) Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'tablet (TABLET)'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'four times daily (QID)'	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '02 Dec 2020'	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '0'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4)	31 Dec 2020 17:37:42
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '25 Dec 2020' reason for change: New Information	(b) (4)	
	Andrea Wendrow (b) (4)	31 Dec 2020 17:37:42
User entered empty.	(b) (4)	
	Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'No (N)'	(b) (4) Lorna Sanchez McCann	03 Dec 2020 15:58:05
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User entered '4'	System	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User entered '1'	System	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:58:11
User entered '804 (804)'	System	03 Dec 2020 15:58:05

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 07:08:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:08:07
Data point term sent to Coder	System	25 Mar 2021 23:35:08
User entered 'Cefdinir'	Andrea Wendrow (b) (4) (b) (4)	25 Mar 2021 23:34:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Tonsilitis'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '300'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'mg (mg)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'twice daily (BID)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '24 Mar 2021'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '0'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:34:52
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 23:34:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 23:34:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 23:34:52

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 10:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 10:09:37
Data point term sent to Coder	System	25 Mar 2021 23:37:09
User entered 'Walgreens Women's Probiotic'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Please review and verify if this can be updated to NO as there is a corresponding AE condition recorded. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 09:02:20
Query 'Per DM CLR: Please review and verify if this can be updated to NO as there is a corresponding AE condition recorded. If yes, please update accordingly.' answered with 'this is a prophylaxis because it is taken in order to prevent diarrhea that would be caused by the antibiotic' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:15:03
User opened query 'Per DM CLR: Please review and verify if this can be updated to NO as there is a corresponding AE condition recorded. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:19:33
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	25 Mar 2021 23:36:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 09:02:34
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'this is taken as a prophylaxis for the antibiotic that was taken for tonsilitis' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:21:46
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:19:26
User entered 'Prevent diarrhea from antibiotic'	Andrea Wendrow (b) (4) (b) (4)	25 Mar 2021 23:36:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '5'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Other (OTHER)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'billion active cultures per capsule'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'twice daily (BID)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '24 Mar 2021'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered '0'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'Yes (Y)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:24:08
	(b) (4)	
User entered 'No (N)'	Andrea Wendrow (b) (4)	25 Mar 2021 23:36:27
	(b) (4)	

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 23:36:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 23:36:27

US3492085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:57:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 23:36:27

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:57:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	31 Dec 2020 17:39:55
User entered 'No (N)'	Andrea Wendrow (b) (4)	10 Sep 2020 14:11:01
	(b) (4), (b) (6)	

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '10 Dec 2020'	Andrea Wendrow (b) (4)	31 Dec 2020 17:40:37
	(b) (4)	

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'Right ovarian cyst removal'	Andrea Wendrow (b) (4)	31 Dec 2020 17:40:37
	(b) (4)	

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered 'Adverse Event (AE)'	Andrea Wendrow (b) (4)	31 Dec 2020 17:40:37
	(b) (4)	

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	31 Dec 2020 17:40:37
	(b) (4)	

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:33:41

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'ultrasound'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:33:41

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:33:41

US3492085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:57:48

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:55
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:33:41

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '04/Dec/2020 09:22'	(b) (4) System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '14/Dec/2020 20:24'	(b) (4) System	14 Dec 2020 20:24:08

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 21:09:30
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 20:24:08

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '04/Jan/2021 21:09'	(b) (4) System	04 Jan 2021 21:09:44

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:21:02
User entered '1'	(b) (4), (b) (6)	04 Jan 2021 21:09:44

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '02/Feb/2021 15:21'	(b) (4) System	02 Feb 2021 15:21:14

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 18:46:24
User entered '1'	(b) (4), (b) (6)	02 Feb 2021 15:21:14

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered '11/Feb/2021 13:46'	(b) (4) System	11 Feb 2021 18:46:55

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 19:07:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:46:55

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '23/Feb/2021 14:07'	(b) (4) System	23 Feb 2021 19:07:34

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 19:07:38
User entered '1'	(b) (4), (b) (6)	23 Feb 2021 19:07:34

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'USA-US101-2020-MRNA-1273-P301000009'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'No (N)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Yes (Y)'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Richard'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Novak'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '808 S. Wood St'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'Chicago'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered 'IL'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:22:42
User entered '60612'	System	04 Dec 2020 14:22:18

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:24:00
User entered 'US'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	02 Mar 2021 16:24:04
Signature has been broken.	System	23 Feb 2021 19:07:34
User entered '6'	System	23 Feb 2021 19:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:39:54
	(b) (4)	
User entered '5'	System	11 Feb 2021 18:46:55
User entered '4'	System	02 Feb 2021 15:21:14
User entered '3'	System	04 Jan 2021 21:09:44
User entered '2'	System	14 Dec 2020 20:24:08
User entered '1'	System	04 Dec 2020 14:22:48

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 07:57:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered '02/Mar/2021 11:24'	(b) (4) System	02 Mar 2021 16:24:04

US3492085

Folder: SAE USA-US101-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 07:57:48

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)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:51
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:42:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:24:04