

US3482267 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:49:35

All time stamps listed in this document are displayed in GMT

US3482267

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

Participant ID

US3482267

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

US3482267

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3482267

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Date of Birth (MMM yyyy)	(b) (6) 1941
Age	78
Age Units	YEARS
Age (Derived)	78
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 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 type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 15:37:33

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

Condition	PRE DIABETES
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

Condition	DRY CHRONIC COUGH, UNKNOWN ETIOLOGY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

Condition	RESTLESS LEG SYNDROME
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)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 01:29:37

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	9:00 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 9:00
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	190 lb
BMI (<i>xxx.x</i>)	28.94981 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 15:37:33

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Date of assessment (*dd MMM yyyy*) 10 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*) UN UNK 1998

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:37:33

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 15:37:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 190347

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 10:29 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 10:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:58	10 SEP 2020 09:58
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 11:03

PC Open Date & Time

10 SEP 2020 10:49

PC Close Date & Time

10 SEP 2020 13:19

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 08:16

PC Open Date & Time

10 SEP 2020 14:14

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:58

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

97.8 °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

12 SEP 2020 18:55

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

13 SEP 2020 19:32

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

98.1 °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

14 SEP 2020 19:37

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 19:45

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

98.0 °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

16 SEP 2020 22:16

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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)

1

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

10 SEP 2020 11:07

PC Open Date & Time

10 SEP 2020 10:49

PC Close Date & Time

10 SEP 2020 13:19

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 08:11

PC Open Date & Time

10 SEP 2020 14:14

PC Close Date & Time

11 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

11 SEP 2020 18:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

12 SEP 2020 18:54

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

13 SEP 2020 19:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

14 SEP 2020 19:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

15 SEP 2020 19:46

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

16 SEP 2020 22:16

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 11:08
PC Open Date & Time	10 SEP 2020 10:49
PC Close Date & Time	10 SEP 2020 13:19

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 11:36
PC Open Date & Time	10 SEP 2020 14:14
PC Close Date & Time	11 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

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 ☒

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

54 of 3139

EAB) (1725)

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:54
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

56 of 3139

EAB) (1725)

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:32
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

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
EAB) (1725)

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US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:36
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

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)

60 of 3139

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:47
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

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 ☒

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 22:17
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3482267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 SEP 2020

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

Comments
If Contact Not Made, please provide Comments

PHONE ATTEMPT #1: LEFT
VOICEMAIL
PHONE ATTEMPT #2: LEFT
VOICEMAIL
PHONE ATTEMPT #3: LEFT
VOICEMAIL
PHONE ATTEMPT #4:
SUCCESSFUL CONTACT

US3482267

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

ATTEMPT #1: LEFT VOICEMAIL
ATTEMPT #2: SUCCESSFUL
CONTACT; ON 23SEP2020 HAD
STRESS TEST - NEGATIVE, HAD
PREVIOUSLY SCHEDULED
LAST YEAR TO MONITOR SOB;
PT WITH MODERATE ASTHMA

US3482267

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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)	8 OCT 2020
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:07
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 12:56
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3482267

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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) 8 OCT 2020

What was the treatment time? (00:00-23:59) 12:17 (24 HR)

Treatment Date and Time (derived) 8 OCT 2020 12:17

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

US3482267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

8 OCT 2020 11:40

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:33	8 OCT 2020 11:33
Nasopharyngeal Swab 2	No		

US3482267

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

98.1 °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 13:35

PC Open Date & Time

08 OCT 2020 12:37

PC Close Date & Time

08 OCT 2020 15:07

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.5 °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	08 OCT 2020 19:16
PC Open Date & Time	08 OCT 2020 16:02
PC Close Date & Time	09 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 22:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

10 OCT 2020 19:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

98.7 °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

11 OCT 2020 19:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

97.7 °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

12 OCT 2020 19:03

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 19:04

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

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.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 19:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 13:38

PC Open Date & Time

08 OCT 2020 12:37

PC Close Date & Time

08 OCT 2020 15:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 19:17

PC Open Date & Time

08 OCT 2020 16:02

PC Close Date & Time

09 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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 OCT 2020 22:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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 OCT 2020 19:04

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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 OCT 2020 19:03

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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 OCT 2020 19:04

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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 OCT 2020 19:05

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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 OCT 2020 19:03

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 13:36
PC Open Date & Time	08 OCT 2020 12:37
PC Close Date & Time	08 OCT 2020 15:07

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 19:18
PC Open Date & Time	08 OCT 2020 16:02
PC Close Date & Time	09 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

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 ☒

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 22:04
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

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EAB) (1725)

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 19:05
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

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)

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US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

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 ☒

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 19:05
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

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 ☒

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 19:06
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

EAB) (1725)

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US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 19:03
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3482267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments "SWITCHED ALLERGY
MEDICINE TO ZYRTEC
If Contact Not Made, please provide Comments VISITED CARDIOLOGIST AND
EVERYTHING WAS FINE"

US3482267

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:29

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	VISIT3

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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) _____

US3482267

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

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.

US3482267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 NOV 2020

Collection time (00:00-23:59)

11:15 (24 HR)

Collection date and time (derived)

5 NOV 2020 11:15

US3482267

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 15:37:33

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 08:15:11
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

17 NOV 2020 01:43:19

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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	21 NOV 2020 09:41:10
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 NOV 2020 08:20:01
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

05 DEC 2020 00:56:08

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 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	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	False
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	12 DEC 2020 10:08:43
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 <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°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	False
Sore throat	False
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 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	19 DEC 2020 07:41:02
Patient Cloud Open Date & Time	19 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
127 of 3139	

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 <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°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
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 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	26 DEC 2020 13:10:46
Patient Cloud Open Date & Time	26 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
129 of 3139	

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 07:42:58

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

09 JAN 2021 06:30:30

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 15:46:03

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 11:32:34
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

30 JAN 2021 07:58:21

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

06 FEB 2021 00:44:41

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 01:28:10
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 07:52:42

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

27 FEB 2021 16:19:08

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 11:33:11
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

13 MAR 2021 16:54:10

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 01:51:41
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

27 MAR 2021 22:44:10

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 APR 2021 12:21:44
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

11 APR 2021 23:19:56

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:30:14

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

26 APR 2021 12:00:56

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 07:20:33

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 243

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 299

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

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

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

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

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

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

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	03 NOV 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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23 FEB 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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02 MAR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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="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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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="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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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="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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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="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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Patient Cloud Open Date & Time	17 SEP 2022 00:01
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Patient Cloud Close Date & Time	21 SEP 2022 23:59
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US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 747

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

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

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

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

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

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

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 ☐

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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="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"/>

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

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

US3482267

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:49:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:19:38

US3482267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

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

Visit date (dd MMM yyyy)	24 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
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US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 11:39
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3482267

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

11:48 (24 HR)

Collection date and time (derived)

24 MAR 2021 11:48

US3482267

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

Date of Contact	12 DEC 2020
Time of Contact	11:04
Date and Time of Contact (derived)	12 DEC 2020 11:04
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>

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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 DEC 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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 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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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"/>

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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 ☐

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	83 %	
O2 Saturation Units	%	
Temperature	96.9 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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"/>

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:32:44

Generated On: 09 Jun 2021 17:49:35

Date of Visit	14 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	14 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3482267

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	15:02 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 15:02
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482267

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3482267

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 DEC 2020

US3482267

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

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

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3482267

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 18:20:50

Generated On: 09 Jun 2021 17:49:35

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3482267

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3482267

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Height	ND - Not Done
Weight	ND - Not Done
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)	13 JAN 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 12:17
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3482267

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Height	ND - Not Done
Weight	ND - Not Done
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)	13 JAN 2021
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 13:35
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3482267

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3482267

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 13:04 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 13:04

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	12:06 (24 HR)
Collection date and time (derived)	13 JAN 2021 12:06

US3482267

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	12:08
Collection Date and Time (derived)	13 JAN 2021 12:08

US3482267

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

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)	10 FEB 2021
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 11:29
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

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)	10 FEB 2021
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 12:35
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3482267

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3482267

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 12:01 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 12:01

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

US3482267

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482267

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482267

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:33:16

Generated On: 09 Jun 2021 17:49:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:39 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 11:39
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	89 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482267

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3482267

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:32:45

Generated On: 09 Jun 2021 17:49:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	11:48 (24 HR)
Collection date and time (derived)	24 MAR 2021 11:48

US3482267

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 03:24:41

Generated On: 09 Jun 2021 17:49:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

AEID

Adverse event

BRUISED ARM AFTER
INJECTION

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)

10 SEP 2020

Start time (00:00-23:59)

10:29 (24 HR)

AE start date and time (derived)

10 SEP 2020 10:29

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

23:59 (24 HR)

AE End Date and Time (derived)

10 SEP 2020 23:59

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

AEID

Adverse event

VASOVAGAL SYNDROME

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)

08 OCT 2020

Start time (00:00-23:59)

12:56 (24 HR)

AE start date and time (derived)

08 OCT 2020 12:56

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 OCT 2020

End time (00:00-23:59)

14:30 (24 HR)

AE End Date and Time (derived)

08 OCT 2020 14:30

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT EXPERIENCED A VASOVAGAL EPISODE 5-10 MINUTES AFTER INJECTION. SEE PROGRESS NOTES FOR DETAILS. DIASTOLIC BP WAS < 60 AND HENCE GRADE 3 PER PROTOCOL.
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 16:19:30

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

AEID	
Adverse event	INTERMITTENT TREMORS
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)	12 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

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

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SUBJECT STATED THEY WERE
EXPERIENCING TREMORS;
WHICH SUBJECT BELIEVES IS
ATTRIBUTED TO CONDITION
[RESTLESS LEG SYNDROME]
DIAGNOSED PRIOR TO STUDY
ENROLLMENT. HOWEVER,
SUBJECT STATES IT IS GETTING
WORSE IN LEFT HANDS.
SUBJECT NOTICED LAST WEEK
[12OCT2020] AND STARTED
TAKING CLONAZEPAM
(ORIGINALLY TAKING
MEDICINE AS NEEDED); TOOK
CLONAZEPAM ONCE IN
OCTOBER TO AID IN
CONDITION.

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)	

US3482267

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

AEID

Adverse event

MACULAR, NON-URTICARIAL
RASH ON BILATERAL HANDS

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)

30 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

US3482267

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SUBJECT REPORTS RASH X2
WEEKS WITH START DATE OF
APPROXIMATELY 30NOV2020.
SITE PROVIDER EXAMINED
SUBJECT DURING ILLNESS
VISIT ON 14DEC2020. RASH
FOUND TO BE
ERYTHEMATOUS/MACULAR
ABOUT 2-3CM IN DIAMETER
OVER DORSAL REGIONS OF
BILATERAL HANDS. HAS
APPOINTMENT SCHEDULED
WITH PCP. REPORTS HAVING
HAD SIMILAR RASH IN THE
PAST RELATED TO HER CATS
AT HOME.

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)	

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

AEID	USA-US106-2020-MRNA-1273-P30 1000010
Adverse event	ACUTE PULMONARY EMBOLI
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	21 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SUBJECT BEGAN
EXPERIENCING SOB (ABOVE
BASELINE) WITH FATIGUE ON
18DEC2020. STUDY TEAM
RECOMMENDED GOING TO ED
FOR WORSENING COVID-19
SYMPTOMS. SUBJECT FOUND
TO HAVE ACUTE PULMONARY
EMBOLI INVOLVING RIGHT
UPPER/LOWER LOBES.
TRIGGER FOR EMBOLUS
UNKNOWN. THOUGHT TO BE
RELATED TO DECREASE IN
ACTIVITY SINCE BEGINNING
OF PANDEMIC. COVID
NEGATIVE. LABILE OXYGEN
READINGS (83%-94%)
REPORTED AT DAY 4
TELEMEDICINE VISIT.

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

AEID	
Adverse event	COMMON COLD
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)	10 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 JAN 2021
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	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	RELATED TO ILLNESS VISIT SYMPTOMS NOTED ON SYMPTOM LOG.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 16:19:30

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AEID	
Adverse event	OSTEOARTHROSIS INVOLVING LOWER LEGS (BILATERAL KNEES), WORSENING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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"/>
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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 16:19:30

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SUBJECT REPORTS THAT
ARTHRITIS IN HER KNEES HAS
WORSENER SINCE 15 DEC 2020.
SHE HAS BEEN TRYING TO GET
AN ORTHOPEDIST
APPOINTMENT.
UPDATE 10MAR 2021: PPT HAS
APPT WITH ORTHO 31MAR 2021
FOR EVAL AND TO DISCUSS
INTERVENTIONS THAT MAY BE
TX OPTIONS. USED TYLENOL
AND DICLOFENAC GEL.
SUBJECT WAS GIVEN A
CORTISONE INJECTION IN
EACH KNEE ON 31 MAR 2021.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication LATANOPROST

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP EACH EYE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input 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 checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication AZOPT

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify DROP EACH EYE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input 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 checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication SIMVASTATIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CORONARY ARTERY DISEASE
PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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 2006	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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="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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication PRAMIPREXOLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication 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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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Name of Medication SYMBICORT 160/4.5 MCG

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 DEC	2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication FOSAMAX

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication DICLOFENAC 1% GEL

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE PAIN
ASSOCIATED WITH
OSTEOARTHRISIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication LORATIDINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ZYTREC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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	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)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		2 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication ITCHING IN HANDS RELATED
TO RASH (AE #4)

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE ASSOCIATED WITH
AE #6

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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)		13 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)		13 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication TERBINAFINE
HYDROCHLORIDE 1%

Prophylaxis Yes ☐
No ☒

Indication RASH ON BILATERAL HANDS
(AE #4)

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ACUTE PULMONARY EMBOLISM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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 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)		26 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 16:22:45

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Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ACUTE PULMONARY EMBOLISM

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication COMMON COLD

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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)		13 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)		13 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"/>

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication HEPARIN HIGH DOSE BOLUS

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLI

Dose per administration 6800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 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)		18 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLI

Dose per administration 15-18

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

If dose unit is Other, specify UNIT/KG/HR

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 CONTINUOUS TITRATED
INFUSION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 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)		20 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENTATION
(ASSOCIATED WITH AE #5)

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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)	21 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)		21 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication FLUOCINONIDE 0.05%

Prophylaxis Yes ☐
No ☒

Indication AE #4 RASH

Dose per administration 0.05

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

If dose unit is Other, specify PERCENT

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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)		15 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN DURING HOSPITAL
ADMISSION (AE #5)

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	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)		19 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)		20 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication KNEE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

Name of Medication CORTISONE

Prophylaxis Yes ☐
No ☒

Indication AE 8 WORSENING
OSTEOARTHRISIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 08 Apr 2021 16:22:45

Generated On: 09 Jun 2021 17:49:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	31 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 22:32:36

Generated On: 09 Jun 2021 17:49:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 22:32:36

Generated On: 09 Jun 2021 17:49:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 SEP 2020	CARDIAC STRESS TEST	Medical History	
18 DEC 2020	CHEST CT	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:49:35

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:49:35

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 ☐

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SAEID	USA-US106-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SAEID	USA-US106-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/DEC/2020 13:25
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

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SAEID	USA-US106-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/JAN/2021 12:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SAEID	USA-US106-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/JAN/2021 13:56
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

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 16:19:30

Generated On: 09 Jun 2021 17:49:35

SAEID	USA-US106-2020-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NADINE
Investigator's Last Name	ROUPHAEL
Site Address: Street	500 IRVIN COURT
Site Address: City	DECATUR
Site Address: State	GA
Site Address: Postal Code	30030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/APR/2021 17:58
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

US3482267 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482267

Form: Participant Creation

Generated On: 09 Jun 2021 17:49:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'US3482267'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:15:06

US3482267

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:06

US3482267

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:15:07

US3482267

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Clinic (Clinic)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:06

US3482267

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'SCRN'	System	10 Sep 2020 13:42:06

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered (b) (6) 1941'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:15:08

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '78'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'YEARS'	System	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '78'	System	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Female (F)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'I'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:49:35

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:42:26

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered '10 Sep 2020'	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Sep 2020'	System	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2020'	System	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered 'Amendment 3 (3)'	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered 'Yes (Y)'	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered empty.	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered empty.	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered 'No (N)'	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:43:28

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:30:54
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:15:07

US3482267

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:49:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'I'	System	10 Sep 2020 13:43:37

US3482267

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:43:37

US3482267

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:49:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:03:43

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	21 Feb 2021 01:29:37
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)	16 Feb 2021 15:28:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 15:28:02
Data point term sent to Coder	System	16 Feb 2021 15:27:23
Coding entries removed.	(b) (4), (b) (6)	16 Feb 2021 15:26:56
Signature has been broken.	(b) (4), (b) (6)	16 Feb 2021 15:26:56
User entered 'MODERATE ASTHMA' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:26:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
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)	22 Sep 2020 11:01:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 11:01:39
Data point term sent to Coder	System	11 Sep 2020 14:05:16
User entered 'moderate asthmaun'	Easton Beshears (b) (4)	11 Sep 2020 14:04:46
	(b) (4)	

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 2018'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 2018'	System	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2018'	System	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:04:46

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 14:06:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:06:45
Data point term sent to Coder	System	11 Sep 2020 14:06:17
User entered 'Pre Diabetes'	Easton Beshears (b) (4)	11 Sep 2020 14:05:30
	(b) (4)	

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'un UNK 1999' reason for change: Data Entry Error	System	14 Sep 2020 17:35:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Easton Beshears (b) (4)	14 Sep 2020 17:35:42
User entered ' 1999' (non-conformant).	(b) (4)	
	System	11 Sep 2020 14:05:30
	Easton Beshears (b) (4)	11 Sep 2020 14:05:30
	(b) (4)	

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 1999'	System	14 Sep 2020 17:35:42
User entered empty.	System	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '1999'	System	14 Sep 2020 17:35:42
User entered empty.	System	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:05:30

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4)	
Query 'Per MM: Please update to reflect the etiology, if known. ' answered with 'NO KNOWN ETIOLOGY, AS PER ORIGINAL ENTRY. PROVIDER SUGESTED ACE INHIBITOR CAUSE AND PARTICIPANT TO FOLLOW UP WITH PCP.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:53:42
	(b) (4), (b) (6)	23 Oct 2020 21:43:39
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Dry cough - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:14:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 10:14:01
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 15:06:29
Coding entries removed.	Easton Beshears (b) (4)	06 Oct 2020 15:06:07
	(b) (4)	
User entered 'DRY CHRONIC COUGH, unknown etiology' reason for change: Data Entry Error	Easton Beshears (b) (4)	06 Oct 2020 15:06:07
	(b) (4)	
User opened query 'Per MM: Please update to reflect the etiology, if known. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:21:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Dry cough - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 14:23:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 14:23:35
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 14:06:17
User entered 'Dry chronic cough'	Easton Beshears (b) (4)	11 Sep 2020 14:06:04
	(b) (4)	

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 2015'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 2015'	System	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2015'	System	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:06:04

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 14:08:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:08:43
Data point term sent to Coder	System	11 Sep 2020 14:07:19
User entered 'hypertension'	Easton Beshears (b) (4)	11 Sep 2020 14:06:59
	(b) (4)	

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 2000'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 2000'	System	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2000'	System	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:06:59

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
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)	11 Sep 2020 14:09:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:09:34
Data point term sent to Coder	System	11 Sep 2020 14:08:21
User entered 'Depression'	Easton Beshears (b) (4)	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 2005'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 2005'	System	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2005'	System	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:07:34

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 14:09:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:09:34
Data point term sent to Coder	System	11 Sep 2020 14:08:22
User entered 'Restless leg syndrome'	Easton Beshears (b) (4)	11 Sep 2020 14:07:55
	(b) (4)	

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 2009'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 2009'	System	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2009'	System	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:07:55

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 14:10:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:10:38
Data point term sent to Coder	System	11 Sep 2020 14:09:24
User entered 'Glaucoma'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 2010'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 2010'	System	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '2010'	System	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	11 Sep 2020 14:08:28

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4)	29 Oct 2020 17:23:32
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4)	29 Oct 2020 17:23:32
Data point term sent to Coders System	(b) (4)	28 Oct 2020 13:35:46
User entered 'Post-menopausal'	(b) (4), (b) (6)	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'Jan 1998'	System	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '1998'	System	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	28 Oct 2020 13:34:51

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
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.	(b) (4) Coder Import (b) (4)	15 Jan 2021 14:58:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 14:58:52
Data point term sent to Coder	System	15 Jan 2021 14:57:28
User entered 'seasonal allergies'	Hollie Macenczak (b) (4)	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 14:57:01

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis, localized, not specified whether primary or secondary - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Jan 2021 13:31:10
Data point term sent to Coder	(b) (4)	
User entered 'osteoarthritis involving lower legs'	System	17 Jan 2021 13:31:10
	Hollie Macenczak (b) (4)	15 Jan 2021 15:46:05
		15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered empty.	System	15 Jan 2021 15:45:43

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '9:00'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '10 Sep 2020 9:00'	System	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '68' in	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50
DataPoint set to visible.	(b) (4) System	10 Sep 2020 13:43:37

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '190' lb	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50
DataPoint set to visible.	(b) (4) System	10 Sep 2020 13:43:37

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered '28.94981'	System	11 Sep 2020 14:09:50
DataPoint set to visible.	System	10 Sep 2020 13:43:37

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'kg/m2'	System	11 Sep 2020 14:09:50
DataPoint set to visible.	System	10 Sep 2020 13:43:37

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'bpm'	System	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'breaths/min'	System	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'mmHg'	System	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User entered 'mmHg'	System	11 Sep 2020 14:09:50

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49

US3482267

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49

US3482267

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:00

US3482267

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:00

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:53:49
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.	(b) (4), (b) (6)	28 Oct 2020 13:34:15
' answered with 'Updated MH ecrf' (Site from DM).		
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:04:52
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Easton Beshears (b) (4) (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'UN UNK 1998' reason for change:	(b) (4)	
Data Entry Error	Easton Beshears (b) (4)	15 Sep 2020 17:44:35
User entered 'un UNK 2020'	(b) (4)	
	Easton Beshears (b) (4)	10 Sep 2020 13:44:26
	(b) (4)	

US3482267

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:49:35

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:44:26

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '0'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'I'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'I'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:49:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:45:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Resides in community with increased peer-to-peer transmission'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:46:17

US3482267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:47:46

US3482267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:47:46

US3482267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[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 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Clinic (Clinic)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 13:47:46

US3482267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'VISIT1'	System	10 Sep 2020 13:47:46

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:14:48

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '190347'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:14:48

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:14:48

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

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 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:51

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

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 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:51

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:51

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:51

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:10:51

US3482267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:49:35

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 04:10:09
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:11:32
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 18:11:24
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 22:52:00
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:55:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:55:57

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User accepted default value 'Pre-Dose (PREDOSE)'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '09:00'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered '10 Sep 2020 09:00'	System	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.9' F reason for change: Data Entry Error	System	14 Sep 2020 17:22:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Easton Beshears (b) (4)	14 Sep 2020 17:22:23
User entered '97.9' (non-conformant).	(b) (4)	
	System	11 Sep 2020 14:12:20
	Easton Beshears (b) (4)	11 Sep 2020 14:12:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Oral (Oral)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '81'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'bpm'	System	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '14'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'breaths/min'	System	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	15 Sep 2020 11:10:47
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 17:22:39
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 14:12:20
User entered '156'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:12:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'mmHg'	System	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '72'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'mmHg'	System	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered missing code ND - Not Done.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:12:20

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User accepted default value 'Post-Dose (POSTDOSE)'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '11:00'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered '10 Sep 2020 11:00'	System	11 Sep 2020 14:15:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.6' F reason for change: Data Entry Error	System	11 Sep 2020 14:20:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Easton Beshears (b) (4)	11 Sep 2020 14:20:27
User entered '97' (non-conformant).	(b) (4)	
	System	11 Sep 2020 14:15:38
	Easton Beshears (b) (4)	11 Sep 2020 14:15:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Oral (Oral)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '97'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'bpm'	System	11 Sep 2020 14:15:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '14'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'breaths/min'	System	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '138'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'mmHg'	System	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '83'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'mmHg'	System	11 Sep 2020 14:15:38

US3482267

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:20:51

US3482267

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:20:51

US3482267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 14:57:37

US3482267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 14:57:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 14:57:37

US3482267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 14:57:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 14:57:37

US3482267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10:29'	(b) (4) Easton Beshears (b) (4)	10 Sep 2020 14:57:37

US3482267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered '10 Sep 2020 10:29'	System	10 Sep 2020 14:57:37

US3482267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Easton Beshears (b) (4)	10 Sep 2020 14:57:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'ONCE'	System	10 Sep 2020 14:57:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 14:57:37

US3482267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:21:57

US3482267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:21:57

US3482267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10:00'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:21:57

US3482267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered '10 Sep 2020 10:00'	System	11 Sep 2020 14:21:57

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:22:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '09:58'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered '10 Sep 2020 09:58'	System	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered empty.	System	11 Sep 2020 14:22:15

US3482267

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	11 Sep 2020 14:22:20

US3482267

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'I'	System	11 Sep 2020 14:22:20

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:03:14', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c00a3d7a-3234-498a-82dc-430e8485ca43' User entered 'Yes (Y)'	System	10 Sep 2020 15:03:49
	System	10 Sep 2020 15:03:49

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:03:25', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c00a3d7a-3234-498a-82dc-430e8485ca43' User entered '97.6'	System	10 Sep 2020 15:03:49
	System	10 Sep 2020 15:03:49

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:03:30', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c00a3d7a-3234-498a-82dc-430e8485ca43'	System	10 Sep 2020 15:03:49
User entered 'No (N)'	System	10 Sep 2020 15:03:49

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:03:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c00a3d7a-3234-498a-82dc-430e8485ca43' User entered '10 Sep 2020 11:03'	System	10 Sep 2020 15:03:49
	System	10 Sep 2020 15:03:49

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 10:49'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 13:19'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:15:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f86a2647-47e5-43c1-a906-0ef2ba4d079b' User entered 'Yes (Y)'	System	11 Sep 2020 12:16:40
	System	11 Sep 2020 12:16:40

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:16:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f86a2647-47e5-43c1-a906-0ef2ba4d079b' User entered '96.6'	System	11 Sep 2020 12:16:40
	System	11 Sep 2020 12:16:40

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:16:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f86a2647-47e5-43c1-a906-0ef2ba4d079b' User entered 'No (N)'	System	11 Sep 2020 12:16:40
	System	11 Sep 2020 12:16:40

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:16:34', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f86a2647-47e5-43c1-a906-0ef2ba4d079b' User entered '11 Sep 2020 08:16'	System	11 Sep 2020 12:16:40
	System	11 Sep 2020 12:16:40

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 14:14'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 2'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:58:34', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7a75af6f-9c51-44e7-b5cf-60a141ec9c7b' User entered 'Yes (Y)'	System	11 Sep 2020 22:59:20
	System	11 Sep 2020 22:59:20

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:58:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7a75af6f-9c51-44e7-b5cf-60a141ec9c7b' User entered '98.3'	System	11 Sep 2020 22:59:20
	System	11 Sep 2020 22:59:20

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:58:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7a75af6f-9c51-44e7-b5cf-60a141ec9c7b'	System	11 Sep 2020 22:59:20
User entered 'No (N)'	System	11 Sep 2020 22:59:20

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:58:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7a75af6f-9c51-44e7-b5cf-60a141ec9c7b' User entered '11 Sep 2020 18:58'	System	11 Sep 2020 22:59:20
	System	11 Sep 2020 22:59:20

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 3'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e8043489-efe9-4f81-87a3-b6052da4af9c' User entered 'Yes (Y)'	System	12 Sep 2020 22:55:35
	System	12 Sep 2020 22:55:35

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:55:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e8043489-efe9-4f81-87a3-b6052da4af9c' User entered '97.8'	System	12 Sep 2020 22:55:35
	System	12 Sep 2020 22:55:35

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:55:15', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e8043489-efe9-4f81-87a3-b6052da4af9c'	System	12 Sep 2020 22:55:35
User entered 'No (N)'	System	12 Sep 2020 22:55:35

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:55:22', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e8043489-efe9-4f81-87a3-b6052da4af9c'	System	12 Sep 2020 22:55:35
User entered '12 Sep 2020 18:55'	System	12 Sep 2020 22:55:35

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 4'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '9b3f6a9f-63dd-45e7-a20d-10f4374f806c' User entered 'Yes (Y)'	System	13 Sep 2020 23:32:08
	System	13 Sep 2020 23:32:08

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:53', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '9b3f6a9f-63dd-45e7-a20d-10f4374f806c' User entered '98.0'	System	13 Sep 2020 23:32:08
	System	13 Sep 2020 23:32:08

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '9b3f6a9f-63dd-45e7-a20d-10f4374f806c'	System	13 Sep 2020 23:32:08
User entered 'No (N)'	System	13 Sep 2020 23:32:08

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:05', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '9b3f6a9f-63dd-45e7-a20d-10f4374f806c'	System	13 Sep 2020 23:32:08
User entered '13 Sep 2020 19:32'	System	13 Sep 2020 23:32:08

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 5'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:37:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7670dfcb-0b84-430e-924e-2869e77e9bcb' User entered 'Yes (Y)'	System	14 Sep 2020 23:37:39
	System	14 Sep 2020 23:37:39

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:37:21', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7670dfcb-0b84-430e-924e-2869e77e9bcb' User entered '98.1'	System	14 Sep 2020 23:37:39
	System	14 Sep 2020 23:37:39

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:37:28', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7670dfcb-0b84-430e-924e-2869e77e9bcb' User entered 'No (N)'	System	14 Sep 2020 23:37:39
	System	14 Sep 2020 23:37:39

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:37:35', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7670dfcb-0b84-430e-924e-2869e77e9bcb' User entered '14 Sep 2020 19:37'	System	14 Sep 2020 23:37:39
	System	14 Sep 2020 23:37:39

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 6'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:45:33', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e23e0a2e-e01c-40a1-8849-28691ee8417a' User entered 'Yes (Y)'	System	15 Sep 2020 23:45:52
	System	15 Sep 2020 23:45:52

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:45:39', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e23e0a2e-e01c-40a1-8849-28691ee8417a' User entered '97.6'	System	15 Sep 2020 23:45:52
	System	15 Sep 2020 23:45:52

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:45:43', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e23e0a2e-e01c-40a1-8849-28691ee8417a' User entered 'No (N)'	System	15 Sep 2020 23:45:52
	System	15 Sep 2020 23:45:52

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:45:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e23e0a2e-e01c-40a1-8849-28691ee8417a' User entered '15 Sep 2020 19:45'	System	15 Sep 2020 23:45:52
	System	15 Sep 2020 23:45:52

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 7'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:15:51', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '492e419f-b24c-439b-9245-f3d5a12b654f' User entered 'Yes (Y)'	System	17 Sep 2020 02:16:13
	System	17 Sep 2020 02:16:13

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:15:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '492e419f-b24c-439b-9245-f3d5a12b654f' User entered '98.0'	System	17 Sep 2020 02:16:13
	System	17 Sep 2020 02:16:13

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:04', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '492e419f-b24c-439b-9245-f3d5a12b654f' User entered 'No (N)'	System	17 Sep 2020 02:16:13
	System	17 Sep 2020 02:16:13

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '492e419f-b24c-439b-9245-f3d5a12b654f' User entered '16 Sep 2020 22:16'	System	17 Sep 2020 02:16:13
	System	17 Sep 2020 02:16:13

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:05:35', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2529f49d-0dc1-49bd-9479-2fa91cb021c1'	System	10 Sep 2020 15:07:48
User entered 'None (1)'	System	10 Sep 2020 15:07:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:05:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2529f49d-0dc1-49bd-9479-2fa91cb021c1' User entered 'No (N)'	System	10 Sep 2020 15:07:48
	System	10 Sep 2020 15:07:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:05:57', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2529f49d-0dc1-49bd-9479-2fa91cb021c1' User entered 'Yes (Y)'	System	10 Sep 2020 15:07:48
	System	10 Sep 2020 15:07:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:07:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2529f49d-0dc1-49bd-9479-2fa91cb021c1' User entered '1'	System	10 Sep 2020 15:07:48
	System	10 Sep 2020 15:07:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:07:22', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2529f49d-0dc1-49bd-9479-2fa91cb021c1' User entered 'None (1)'	System	10 Sep 2020 15:07:48
	System	10 Sep 2020 15:07:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:07:45', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2529f49d-0dc1-49bd-9479-2fa91cb021c1' User entered '10 Sep 2020 11:07'	System	10 Sep 2020 15:07:48
	System	10 Sep 2020 15:07:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 10:49'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 13:19'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:10:42', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5325b2e9-aa87-4b6e-8329-bc8499bd1396'	System	11 Sep 2020 12:11:35
User entered 'None (1)'	System	11 Sep 2020 12:11:35

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:10:48', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5325b2e9-aa87-4b6e-8329-bc8499bd1396' User entered 'No (N)'	System	11 Sep 2020 12:11:35
	System	11 Sep 2020 12:11:35

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:10:55', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5325b2e9-aa87-4b6e-8329-bc8499bd1396' User entered 'No (N)'	System	11 Sep 2020 12:11:35
	System	11 Sep 2020 12:11:35

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:11:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5325b2e9-aa87-4b6e-8329-bc8499bd1396'	System	11 Sep 2020 12:11:35
User entered 'None (1)'	System	11 Sep 2020 12:11:35

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T08:11:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5325b2e9-aa87-4b6e-8329-bc8499bd1396'	System	11 Sep 2020 12:11:35
User entered '11 Sep 2020 08:11'	System	11 Sep 2020 12:11:35

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 14:14'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 2'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a6decd5f-ae60-45ee-aa05-6cb760af1566'	System	11 Sep 2020 22:59:48
User entered 'None (1)'	System	11 Sep 2020 22:59:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a6decd5f-ae60-45ee-aa05-6cb760af1566'	System	11 Sep 2020 22:59:48
User entered 'No (N)'	System	11 Sep 2020 22:59:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a6decd5f-ae60-45ee-aa05-6cb760af1566'	System	11 Sep 2020 22:59:48
User entered 'No (N)'	System	11 Sep 2020 22:59:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:29', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a6decd5f-ae60-45ee-aa05-6cb760af1566'	System	11 Sep 2020 22:59:48
User entered 'None (1)'	System	11 Sep 2020 22:59:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:37', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a6decd5f-ae60-45ee-aa05-6cb760af1566'	System	11 Sep 2020 22:59:48
User entered '11 Sep 2020 18:59'	System	11 Sep 2020 22:59:48

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 3'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:53:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '674998f1-5729-4537-a548-784e32bc56a8' User entered 'None (1)'	System	12 Sep 2020 22:54:02
	System	12 Sep 2020 22:54:02

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:53:37', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '674998f1-5729-4537-a548-784e32bc56a8' User entered 'No (N)'	System	12 Sep 2020 22:54:02
	System	12 Sep 2020 22:54:02

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:53:40', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '674998f1-5729-4537-a548-784e32bc56a8' User entered 'No (N)'	System	12 Sep 2020 22:54:02
	System	12 Sep 2020 22:54:02

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:53:53', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '674998f1-5729-4537-a548-784e32bc56a8' User entered 'None (1)'	System	12 Sep 2020 22:54:02
	System	12 Sep 2020 22:54:02

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '674998f1-5729-4537-a548-784e32bc56a8' User entered '12 Sep 2020 18:54'	System	12 Sep 2020 22:54:02
	System	12 Sep 2020 22:54:02

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 4'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:09', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c2d0a744-4380-49c7-af81-ec0d92ddf2a3'	System	13 Sep 2020 23:31:37
User entered 'None (1)'	System	13 Sep 2020 23:31:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:14', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c2d0a744-4380-49c7-af81-ec0d92ddf2a3'	System	13 Sep 2020 23:31:37
User entered 'No (N)'	System	13 Sep 2020 23:31:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c2d0a744-4380-49c7-af81-ec0d92ddf2a3'	System	13 Sep 2020 23:31:37
User entered 'No (N)'	System	13 Sep 2020 23:31:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c2d0a744-4380-49c7-af81-ec0d92ddf2a3'	System	13 Sep 2020 23:31:37
User entered 'None (1)'	System	13 Sep 2020 23:31:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:31:35', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c2d0a744-4380-49c7-af81-ec0d92ddf2a3' User entered '13 Sep 2020 19:31'	System	13 Sep 2020 23:31:37
	System	13 Sep 2020 23:31:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 5'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:01', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '163156b1-2fcd-46b0-b776-bc9b0c810473'	System	14 Sep 2020 23:35:37
User entered 'None (1)'	System	14 Sep 2020 23:35:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:05', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '163156b1-2fcd-46b0-b776-bc9b0c810473' User entered 'No (N)'	System	14 Sep 2020 23:35:37
	System	14 Sep 2020 23:35:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:09', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '163156b1-2fcd-46b0-b776-bc9b0c810473' User entered 'No (N)'	System	14 Sep 2020 23:35:37
	System	14 Sep 2020 23:35:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:28', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '163156b1-2fcd-46b0-b776-bc9b0c810473'	System	14 Sep 2020 23:35:37
User entered 'None (1)'	System	14 Sep 2020 23:35:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:33', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '163156b1-2fcd-46b0-b776-bc9b0c810473' User entered '14 Sep 2020 19:35'	System	14 Sep 2020 23:35:37
	System	14 Sep 2020 23:35:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 6'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:46:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f1ac9ee6-215d-4dbc-8d90-e500cc450bd4'	System	15 Sep 2020 23:46:53
User entered 'None (1)'	System	15 Sep 2020 23:46:53

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:46:21', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f1ac9ee6-215d-4dbc-8d90-e500cc450bd4'	System	15 Sep 2020 23:46:53
User entered 'No (N)'	System	15 Sep 2020 23:46:53

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:46:25', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f1ac9ee6-215d-4dbc-8d90-e500cc450bd4' User entered 'No (N)'	System	15 Sep 2020 23:46:53
	System	15 Sep 2020 23:46:53

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:46:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f1ac9ee6-215d-4dbc-8d90-e500cc450bd4'	System	15 Sep 2020 23:46:53
User entered 'None (1)'	System	15 Sep 2020 23:46:53

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:46:48', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f1ac9ee6-215d-4dbc-8d90-e500cc450bd4' User entered '15 Sep 2020 19:46'	System	15 Sep 2020 23:46:53
	System	15 Sep 2020 23:46:53

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 7'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:20', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bee91e5c-61fb-4ed2-aaf2-2079c2498d6d'	System	17 Sep 2020 02:16:42
User entered 'None (1)'	System	17 Sep 2020 02:16:42

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bee91e5c-61fb-4ed2-aaf2-2079c2498d6d'	System	17 Sep 2020 02:16:42
User entered 'No (N)'	System	17 Sep 2020 02:16:42

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bee91e5c-61fb-4ed2-aaf2-2079c2498d6d' User entered 'No (N)'	System	17 Sep 2020 02:16:42
	System	17 Sep 2020 02:16:42

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bee91e5c-61fb-4ed2-aaf2-2079c2498d6d' User entered 'None (1)'	System	17 Sep 2020 02:16:42
	System	17 Sep 2020 02:16:42

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bee91e5c-61fb-4ed2-aaf2-2079c2498d6d'	System	17 Sep 2020 02:16:42
User entered '16 Sep 2020 22:16'	System	17 Sep 2020 02:16:42

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:09', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'None (0)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:15', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'None (0)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'None (0)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:22', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'None (0)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:25', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'None (0)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:28', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'None (0)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered 'No (N)'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-10T11:08:51', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'f015ee3d-ff96-41ee-bb65-149d5461985a' User entered '10 Sep 2020 11:08'	System	10 Sep 2020 15:08:54
	System	10 Sep 2020 15:08:54

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 10:49'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 13:19'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:35:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09'	System	11 Sep 2020 15:36:10
User entered 'None (0)'	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:35:42', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09'	System	11 Sep 2020 15:36:10
User entered 'No interference with activity (1)'	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:35:45', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09' User entered 'None (0)'	System	11 Sep 2020 15:36:10
	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:35:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09' User entered 'None (0)'	System	11 Sep 2020 15:36:10
	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:35:53', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09' User entered 'None (0)'	System	11 Sep 2020 15:36:10
	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:35:56', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09' User entered 'None (0)'	System	11 Sep 2020 15:36:10
	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:36:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09' User entered 'No (N)'	System	11 Sep 2020 15:36:10
	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T11:36:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c6579c5a-3f92-4760-8879-c502d4ac5a09'	System	11 Sep 2020 15:36:10
User entered '11 Sep 2020 11:36'	System	11 Sep 2020 15:36:10

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Sep 2020 14:14'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 2'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:48', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered 'None (0)'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T18:59:56', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13'	System	11 Sep 2020 23:00:53
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T19:00:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered 'None (0)'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T19:00:04', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered 'None (0)'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T19:00:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered 'None (0)'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T19:00:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered 'None (0)'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T19:00:15', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered 'No (N)'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-11T19:00:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '26c16de9-36b8-4caa-9470-86f286e02e13' User entered '11 Sep 2020 19:00'	System	11 Sep 2020 23:00:53
	System	11 Sep 2020 23:00:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 3'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:13', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'None (0)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:18', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'None (0)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:20', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'None (0)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:23', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'None (0)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'None (0)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:33', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'None (0)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:36', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered 'No (N)'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-12T18:54:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e9aa15fd-7f37-4816-8d07-cfce0dc4aafe' User entered '12 Sep 2020 18:54'	System	12 Sep 2020 22:55:25
	System	12 Sep 2020 22:55:25

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 4'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'None (0)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'None (0)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'None (0)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:22', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'None (0)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'None (0)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:29', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'None (0)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:33', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered 'No (N)'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-13T19:32:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1e41b78d-a3a8-4222-9fc0-3dc84c748c7f' User entered '13 Sep 2020 19:32'	System	13 Sep 2020 23:32:47
	System	13 Sep 2020 23:32:47

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 5'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:39', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'None (0)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:45', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'None (0)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'None (0)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:52', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'None (0)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:55', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'None (0)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:35:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'None (0)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:36:02', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200' User entered 'No (N)'	System	14 Sep 2020 23:36:14
	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-14T19:36:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '5f307e05-5932-45a6-a652-33fbab392200'	System	14 Sep 2020 23:36:14
User entered '14 Sep 2020 19:36'	System	14 Sep 2020 23:36:14

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 6'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:03', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered 'None (0)'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821'	System	15 Sep 2020 23:47:53
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:13', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered 'None (0)'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered 'None (0)'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered 'None (0)'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered 'None (0)'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered 'No (N)'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-15T19:47:52', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b5c473ae-1c5b-4ce8-819b-886dc2e35821' User entered '15 Sep 2020 19:47'	System	15 Sep 2020 23:47:53
	System	15 Sep 2020 23:47:53

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 7'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'None (0)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'None (0)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'None (0)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:52', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'None (0)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:55', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'None (0)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:16:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'None (0)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:17:02', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered 'No (N)'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-09-16T22:17:07', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3b6b0646-3352-4113-b69a-f11a3cb9f2a2' User entered '16 Sep 2020 22:17'	System	17 Sep 2020 02:17:09
	System	17 Sep 2020 02:17:09

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:57:37

US3482267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	17 Sep 2020 15:04:57

US3482267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 04:48:36
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'attempted to reach subject 3 times by phone within window, but was unsuccessful. Was able to successfully contact subject on 21 Sep 2020' (Site from System).	Easton Beshears (b) (4) (b) (4)	21 Sep 2020 16:59:43
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 16:58:29
User entered '21 Sep 2020' reason for change: Data Entry Error	Easton Beshears (b) (4) (b) (4)	21 Sep 2020 16:58:29
User entered '17 Sep 2020'	Easton Beshears (b) (4) (b) (4)	17 Sep 2020 15:04:57

US3482267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Easton Beshears (b) (4)	21 Sep 2020 16:58:29
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Easton Beshears (b) (4)	17 Sep 2020 15:04:57
	(b) (4)	

US3482267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Phone attempt #1: LEFT VOICEMAIL	(b) (4)	
Phone attempt #2: LEFT VOICEMAIL	Easton Beshears (b) (4)	21 Sep 2020 16:58:29
Phone attempt #3: LEFT VOICEMAIL	(b) (4)	
Phone attempt #4: Successful contact' reason for change: Data Entry Error		
User entered 'LEFT VOICEMAIL #1	Easton Beshears (b) (4)	21 Sep 2020 16:40:51
LEFT VOICEMAIL #2	(b) (4)	
LEFT VOICEMAIL #3' reason for change: Data Entry Error		
User entered 'LEFT VOICEMAIL	Easton Beshears (b) (4)	17 Sep 2020 20:06:28
Left voicemail' reason for change: Data Entry Error	(b) (4)	
User entered 'left voicemail'	Easton Beshears (b) (4)	17 Sep 2020 15:04:57
	(b) (4)	

US3482267

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	17 Sep 2020 15:05:02

US3482267

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'I'	System	17 Sep 2020 15:05:02

US3482267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	24 Sep 2020 18:59:24

US3482267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	25 Sep 2020 13:42:18
User entered '24 Sep 2020'	(b) (4)	
	Easton Beshears (b) (4)	24 Sep 2020 18:59:24
	(b) (4)	

US3482267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Easton Beshears (b) (4)	25 Sep 2020 13:42:18
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Easton Beshears (b) (4)	24 Sep 2020 18:59:24
	(b) (4)	

US3482267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User closed query 'Per DM CLR: Comment = ON 23SEP2020 HAD STRESS TEST - NEGATIVE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 11:51:36
Query 'Per DM CLR: Comment = ON 23SEP2020 HAD STRESS TEST - NEGATIVE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate.' answered with 'Confirmed. This procedure is already listed on con procedures.' (Site from DM).	Amy Anderson (b) (4) (b) (4)	27 Oct 2020 14:36:58
User opened query 'Per DM CLR: Comment = ON 23SEP2020 HAD STRESS TEST - NEGATIVE. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant Procedure page as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:43:25
User entered 'ATTEMPT #1: LEFT VOICEMAIL Attempt #2: successful contact; on 23SEP2020 had stress test - negative, had previously scheduled last year to monitor SOB; pt with moderate asthma' reason for change: Data Entry Error	Easton Beshears (b) (4) (b) (4)	25 Sep 2020 13:42:18
User entered 'Attempt #1: left voicemail'	Easton Beshears (b) (4) (b) (4)	24 Sep 2020 18:59:24

US3482267

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	24 Sep 2020 18:59:31

US3482267

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:02:56
User entered 'I'	System	24 Sep 2020 18:59:31

US3482267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:43:05

US3482267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered '1 Oct 2020'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:43:05

US3482267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:43:05

US3482267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered empty.	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:43:05

US3482267

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:02
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:43:58

US3482267

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:02
User entered 'I'	System	02 Oct 2020 19:43:58

US3482267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:51:52

US3482267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:51:52

US3482267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Clinic (Clinic)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:51:52

US3482267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'VISIT2'	System	08 Oct 2020 15:51:52

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User accepted default value 'Pre-Dose (PREDOSE)'	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '11:07'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered '8 Oct 2020 11:07'	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '98.0' F	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Oral (Oral)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '95'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'bpm'	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '16'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'breaths/min'	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '143'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'mmHg'	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '67'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'mmHg'	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User accepted default value 'Post-Dose (POSTDOSE)'	Easton Beshears (b) (4) (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
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	09 Oct 2020 17:32:43
User entered 'Yes (Y)' reason for change: Data Entry Error	System	09 Oct 2020 17:32:43
User opened query 'Data is required. Please complete.' (Site from System).	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	System	08 Oct 2020 15:53:17
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '12:56' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered '8 Oct 2020 12:56'	System	09 Oct 2020 17:32:43
User entered empty.	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '99' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
	(b) (4)	
User entered empty.	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'bpm'	System	09 Oct 2020 17:32:43
User entered empty.	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'breaths/min'	System	09 Oct 2020 17:32:43
User entered empty.	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '119' reason for change: Data Entry Error	(b) (4)	
	Easton Beshears (b) (4)	09 Oct 2020 17:32:43
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	08 Oct 2020 15:53:17
	(b) (4)	

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'mmHg'	System	09 Oct 2020 17:32:43
User entered empty.	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
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)	12 Oct 2020 17:15:44
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 'CS - participant experienced vasovagal syndrome' (Site from System).	Easton Beshears (b) (4) (b) (4)	09 Oct 2020 17:51:13
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).		09 Oct 2020 17:32:43
User entered '58' reason for change: Data Entry Error	Easton Beshears (b) (4) (b) (4)	09 Oct 2020 17:32:43
User entered empty.	Easton Beshears (b) (4) (b) (4)	08 Oct 2020 15:53:17

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'mmHg'	System	09 Oct 2020 17:32:43
User entered empty.	System	08 Oct 2020 15:53:17

US3482267

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:55

US3482267

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:53:55

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '12:17'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered '8 Oct 2020 12:17'	System	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'ONCE'	System	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 16:45:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:54:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:54:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '11:40'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:54:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered '8 Oct 2020 11:40'	System	08 Oct 2020 15:54:43

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '8 Oct 2020'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Easton Beshears (b) (4) (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '11:33'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered '8 Oct 2020 11:33'	System	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Easton Beshears (b) (4) (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:49:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered empty.	System	08 Oct 2020 15:55:03

US3482267

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	08 Oct 2020 21:08:27

US3482267

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'I'	System	08 Oct 2020 21:08:27

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:34:48', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'd929dc94-2c66-4af1-951a-d98a49306f2c' User entered 'Yes (Y)'	System	08 Oct 2020 17:35:21
	System	08 Oct 2020 17:35:21

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:34:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'd929dc94-2c66-4af1-951a-d98a49306f2c' User entered '98.1'	System	08 Oct 2020 17:35:21
	System	08 Oct 2020 17:35:21

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:07', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'd929dc94-2c66-4af1-951a-d98a49306f2c' User entered 'No (N)'	System	08 Oct 2020 17:35:21
	System	08 Oct 2020 17:35:21

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:18', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'd929dc94-2c66-4af1-951a-d98a49306f2c' User entered '08 Oct 2020 13:35'	System	08 Oct 2020 17:35:21
	System	08 Oct 2020 17:35:21

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 12:37'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 15:07'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:15:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '64c1277b-d0bb-4d82-91cc-8a720e81e6b4' User entered 'Yes (Y)'	System	08 Oct 2020 23:16:24
	System	08 Oct 2020 23:16:24

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:06', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '64c1277b-d0bb-4d82-91cc-8a720e81e6b4' User entered '97.5'	System	08 Oct 2020 23:16:24
	System	08 Oct 2020 23:16:24

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '64c1277b-d0bb-4d82-91cc-8a720e81e6b4' User entered 'No (N)'	System	08 Oct 2020 23:16:24
	System	08 Oct 2020 23:16:24

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:22', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '64c1277b-d0bb-4d82-91cc-8a720e81e6b4' User entered '08 Oct 2020 19:16'	System	08 Oct 2020 23:16:24
	System	08 Oct 2020 23:16:24

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 16:02'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 2'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:02:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bd0d7096-1689-4dde-bc4b-b4be6da92a5f' User entered 'Yes (Y)'	System	10 Oct 2020 02:02:48
	System	10 Oct 2020 02:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:02:34', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bd0d7096-1689-4dde-bc4b-b4be6da92a5f' User entered '97.6'	System	10 Oct 2020 02:02:48
	System	10 Oct 2020 02:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:02:40', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bd0d7096-1689-4dde-bc4b-b4be6da92a5f' User entered 'No (N)'	System	10 Oct 2020 02:02:48
	System	10 Oct 2020 02:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:02:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'bd0d7096-1689-4dde-bc4b-b4be6da92a5f' User entered '09 Oct 2020 22:02'	System	10 Oct 2020 02:02:48
	System	10 Oct 2020 02:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 3'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:03:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '89629054-8f19-41b3-bbcb-36ebc7aae6a0' User entered 'Yes (Y)'	System	10 Oct 2020 23:03:58
	System	10 Oct 2020 23:03:58

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:03:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '89629054-8f19-41b3-bbcb-36ebc7aae6a0' User entered '98.0'	System	10 Oct 2020 23:03:58
	System	10 Oct 2020 23:03:58

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:03:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '89629054-8f19-41b3-bbcb-36ebc7aae6a0'	System	10 Oct 2020 23:03:58
User entered 'No (N)'	System	10 Oct 2020 23:03:58

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:03:54', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '89629054-8f19-41b3-bbcb-36ebc7aae6a0' User entered '10 Oct 2020 19:03'	System	10 Oct 2020 23:03:58
	System	10 Oct 2020 23:03:58

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 4'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:02:13', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '322675cf-d7da-47a1-bb2f-cf8f1ab7add6' User entered 'Yes (Y)'	System	11 Oct 2020 23:02:38
	System	11 Oct 2020 23:02:38

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:02:21', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '322675cf-d7da-47a1-bb2f-cf8f1ab7add6' User entered '98.7'	System	11 Oct 2020 23:02:38
	System	11 Oct 2020 23:02:38

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:02:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '322675cf-d7da-47a1-bb2f-cf8f1ab7add6'	System	11 Oct 2020 23:02:38
User entered 'No (N)'	System	11 Oct 2020 23:02:38

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:02:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '322675cf-d7da-47a1-bb2f-cf8f1ab7add6' User entered '11 Oct 2020 19:02'	System	11 Oct 2020 23:02:38
	System	11 Oct 2020 23:02:38

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 5'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:05', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '757d131e-f55b-4856-8135-c2e20926e41f' User entered 'Yes (Y)'	System	12 Oct 2020 23:03:35
	System	12 Oct 2020 23:03:35

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:13', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '757d131e-f55b-4856-8135-c2e20926e41f' User entered '97.7'	System	12 Oct 2020 23:03:35
	System	12 Oct 2020 23:03:35

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '757d131e-f55b-4856-8135-c2e20926e41f' User entered 'No (N)'	System	12 Oct 2020 23:03:35
	System	12 Oct 2020 23:03:35

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '757d131e-f55b-4856-8135-c2e20926e41f' User entered '12 Oct 2020 19:03'	System	12 Oct 2020 23:03:35
	System	12 Oct 2020 23:03:35

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 6'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:04:09', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a3595017-82a4-4f15-a388-3228b29aa066' User entered 'Yes (Y)'	System	13 Oct 2020 23:04:45
	System	13 Oct 2020 23:04:45

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:04:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a3595017-82a4-4f15-a388-3228b29aa066' User entered '98.2'	System	13 Oct 2020 23:04:45
	System	13 Oct 2020 23:04:45

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:04:37', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a3595017-82a4-4f15-a388-3228b29aa066'	System	13 Oct 2020 23:04:45
User entered 'No (N)'	System	13 Oct 2020 23:04:45

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:04:42', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a3595017-82a4-4f15-a388-3228b29aa066' User entered '13 Oct 2020 19:04'	System	13 Oct 2020 23:04:45
	System	13 Oct 2020 23:04:45

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 7'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:02:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e3252fc9-ac1f-4cfb-a48d-b150ff4569ef' User entered 'Yes (Y)'	System	14 Oct 2020 23:02:48
	System	14 Oct 2020 23:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:02:36', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e3252fc9-ac1f-4cfb-a48d-b150ff4569ef' User entered '98.7'	System	14 Oct 2020 23:02:48
	System	14 Oct 2020 23:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:02:42', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e3252fc9-ac1f-4cfb-a48d-b150ff4569ef' User entered 'No (N)'	System	14 Oct 2020 23:02:48
	System	14 Oct 2020 23:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:02:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e3252fc9-ac1f-4cfb-a48d-b150ff4569ef' User entered '14 Oct 2020 19:02'	System	14 Oct 2020 23:02:48
	System	14 Oct 2020 23:02:48

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:36:51', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4fbb0acc-c597-4a08-be43-575cc6252dd6'	System	08 Oct 2020 17:38:07
User entered 'None (1)'	System	08 Oct 2020 17:38:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:37:41', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4fbb0acc-c597-4a08-be43-575cc6252dd6'	System	08 Oct 2020 17:38:07
User entered 'No (N)'	System	08 Oct 2020 17:38:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:37:45', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4fbb0acc-c597-4a08-be43-575cc6252dd6' User entered 'No (N)'	System	08 Oct 2020 17:38:07
	System	08 Oct 2020 17:38:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:37:55', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4fbb0acc-c597-4a08-be43-575cc6252dd6'	System	08 Oct 2020 17:38:07
User entered 'None (1)'	System	08 Oct 2020 17:38:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:38:02', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4fbb0acc-c597-4a08-be43-575cc6252dd6' User entered '08 Oct 2020 13:38'	System	08 Oct 2020 17:38:07
	System	08 Oct 2020 17:38:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 12:37'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 15:07'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '991a0579-d795-431b-a167-2cfe9e46542b' User entered 'None (1)'	System	08 Oct 2020 23:17:09
	System	08 Oct 2020 23:17:09

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '991a0579-d795-431b-a167-2cfe9e46542b' User entered 'No (N)'	System	08 Oct 2020 23:17:09
	System	08 Oct 2020 23:17:09

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:53', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '991a0579-d795-431b-a167-2cfe9e46542b' User entered 'No (N)'	System	08 Oct 2020 23:17:09
	System	08 Oct 2020 23:17:09

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:16:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '991a0579-d795-431b-a167-2cfe9e46542b' User entered 'None (1)'	System	08 Oct 2020 23:17:09
	System	08 Oct 2020 23:17:09

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:07', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '991a0579-d795-431b-a167-2cfe9e46542b' User entered '08 Oct 2020 19:17'	System	08 Oct 2020 23:17:09
	System	08 Oct 2020 23:17:09

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 16:02'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 2'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:02:56', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6d2c2bb0-0e5d-4ba2-906d-f97d841efbb3'	System	10 Oct 2020 02:03:20
User entered 'None (1)'	System	10 Oct 2020 02:03:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6d2c2bb0-0e5d-4ba2-906d-f97d841efbb3'	System	10 Oct 2020 02:03:20
User entered 'No (N)'	System	10 Oct 2020 02:03:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6d2c2bb0-0e5d-4ba2-906d-f97d841efbb3'	System	10 Oct 2020 02:03:20
User entered 'No (N)'	System	10 Oct 2020 02:03:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6d2c2bb0-0e5d-4ba2-906d-f97d841efbb3'	System	10 Oct 2020 02:03:20
User entered 'None (1)'	System	10 Oct 2020 02:03:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:18', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6d2c2bb0-0e5d-4ba2-906d-f97d841efbb3' User entered '09 Oct 2020 22:03'	System	10 Oct 2020 02:03:20
	System	10 Oct 2020 02:03:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 3'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:03:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '74efa391-5272-4cc7-8017-40d0ed65c469'	System	10 Oct 2020 23:04:20
User entered 'None (1)'	System	10 Oct 2020 23:04:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:03', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '74efa391-5272-4cc7-8017-40d0ed65c469' User entered 'No (N)'	System	10 Oct 2020 23:04:20
	System	10 Oct 2020 23:04:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:06', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '74efa391-5272-4cc7-8017-40d0ed65c469' User entered 'No (N)'	System	10 Oct 2020 23:04:20
	System	10 Oct 2020 23:04:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '74efa391-5272-4cc7-8017-40d0ed65c469'	System	10 Oct 2020 23:04:20
User entered 'None (1)'	System	10 Oct 2020 23:04:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '74efa391-5272-4cc7-8017-40d0ed65c469' User entered '10 Oct 2020 19:04'	System	10 Oct 2020 23:04:20
	System	10 Oct 2020 23:04:20

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 4'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:02:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c06a654f-923d-422d-b76f-795f6f26f9c0'	System	11 Oct 2020 23:03:19
User entered 'None (1)'	System	11 Oct 2020 23:03:19

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c06a654f-923d-422d-b76f-795f6f26f9c0' User entered 'No (N)'	System	11 Oct 2020 23:03:19
	System	11 Oct 2020 23:03:19

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:05', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c06a654f-923d-422d-b76f-795f6f26f9c0' User entered 'No (N)'	System	11 Oct 2020 23:03:19
	System	11 Oct 2020 23:03:19

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c06a654f-923d-422d-b76f-795f6f26f9c0'	System	11 Oct 2020 23:03:19
User entered 'None (1)'	System	11 Oct 2020 23:03:19

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c06a654f-923d-422d-b76f-795f6f26f9c0' User entered '11 Oct 2020 19:03'	System	11 Oct 2020 23:03:19
	System	11 Oct 2020 23:03:19

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 5'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:43', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dab728ed-4d13-42ee-a497-63546792b36a'	System	12 Oct 2020 23:04:07
User entered 'None (1)'	System	12 Oct 2020 23:04:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dab728ed-4d13-42ee-a497-63546792b36a' User entered 'No (N)'	System	12 Oct 2020 23:04:07
	System	12 Oct 2020 23:04:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:55', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dab728ed-4d13-42ee-a497-63546792b36a' User entered 'No (N)'	System	12 Oct 2020 23:04:07
	System	12 Oct 2020 23:04:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:03:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dab728ed-4d13-42ee-a497-63546792b36a'	System	12 Oct 2020 23:04:07
User entered 'None (1)'	System	12 Oct 2020 23:04:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:04', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dab728ed-4d13-42ee-a497-63546792b36a' User entered '12 Oct 2020 19:04'	System	12 Oct 2020 23:04:07
	System	12 Oct 2020 23:04:07

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 6'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:04:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '68a38650-971c-44ca-8b0c-ef6a20e88908'	System	13 Oct 2020 23:05:33
User entered 'None (1)'	System	13 Oct 2020 23:05:33

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:03', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '68a38650-971c-44ca-8b0c-ef6a20e88908' User entered 'No (N)'	System	13 Oct 2020 23:05:33
	System	13 Oct 2020 23:05:33

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '68a38650-971c-44ca-8b0c-ef6a20e88908' User entered 'No (N)'	System	13 Oct 2020 23:05:33
	System	13 Oct 2020 23:05:33

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '68a38650-971c-44ca-8b0c-ef6a20e88908' User entered 'None (1)'	System	13 Oct 2020 23:05:33
	System	13 Oct 2020 23:05:33

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:28', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '68a38650-971c-44ca-8b0c-ef6a20e88908' User entered '13 Oct 2020 19:05'	System	13 Oct 2020 23:05:33
	System	13 Oct 2020 23:05:33

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 7'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:02:54', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eadec5d5-5014-4bfa-a96b-8690c86f4d0d'	System	14 Oct 2020 23:03:12
User entered 'None (1)'	System	14 Oct 2020 23:03:12

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:02:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eadec5d5-5014-4bfa-a96b-8690c86f4d0d' User entered 'No (N)'	System	14 Oct 2020 23:03:12
	System	14 Oct 2020 23:03:12

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:02', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eadec5d5-5014-4bfa-a96b-8690c86f4d0d' User entered 'No (N)'	System	14 Oct 2020 23:03:12
	System	14 Oct 2020 23:03:12

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:05', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eadec5d5-5014-4bfa-a96b-8690c86f4d0d' User entered 'None (1)'	System	14 Oct 2020 23:03:12
	System	14 Oct 2020 23:03:12

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eadec5d5-5014-4bfa-a96b-8690c86f4d0d' User entered '14 Oct 2020 19:03'	System	14 Oct 2020 23:03:12
	System	14 Oct 2020 23:03:12

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered 'None (0)'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:36', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered 'None (0)'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:39', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered 'None (0)'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:43', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered 'None (0)'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered 'None (0)'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:35:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered 'None (0)'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:36:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517'	System	08 Oct 2020 17:36:41
User entered 'No (N)'	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T13:36:39', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eb97415a-f8e0-4815-a40c-76c7e27dd517' User entered '08 Oct 2020 13:36'	System	08 Oct 2020 17:36:41
	System	08 Oct 2020 17:36:41

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 12:37'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 15:07'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:15', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'None (0)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'None (0)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'None (0)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:36', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'None (0)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:40', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'None (0)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'None (0)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:17:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered 'No (N)'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-08T19:18:01', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c05e5458-52cd-43f3-8899-78dcceb53ab2' User entered '08 Oct 2020 19:18'	System	08 Oct 2020 23:18:06
	System	08 Oct 2020 23:18:06

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '08 Oct 2020 16:02'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 2'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'None (0)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:36', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'None (0)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:40', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'None (0)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:43', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'None (0)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'None (0)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'None (0)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:03:57', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered 'No (N)'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-09T22:04:04', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '151c27fb-4b48-4edf-b2df-f142688c6763' User entered '09 Oct 2020 22:04'	System	10 Oct 2020 02:04:09
	System	10 Oct 2020 02:04:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 3'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'None (0)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'None (0)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:35', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'None (0)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'None (0)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:42', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'None (0)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'None (0)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:04:51', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered 'No (N)'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-10T19:05:12', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '7f611dc8-d807-4e18-a92e-c097fd8cfd4e' User entered '10 Oct 2020 19:05'	System	10 Oct 2020 23:05:14
	System	10 Oct 2020 23:05:14

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 4'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'None (0)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'None (0)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:33', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'None (0)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:36', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'None (0)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:41', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'None (0)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'None (0)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered 'No (N)'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-11T19:03:54', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ad6429ed-896a-433a-8a28-999d1ab42326' User entered '11 Oct 2020 19:03'	System	11 Oct 2020 23:03:56
	System	11 Oct 2020 23:03:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 5'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:15', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'None (0)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'None (0)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:20', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'None (0)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:24', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'None (0)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:35', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'None (0)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'None (0)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:04:52', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered 'No (N)'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-12T19:05:04', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'eddf009b-484e-497a-96a6-4fed05cd1709' User entered '12 Oct 2020 19:05'	System	12 Oct 2020 23:05:09
	System	12 Oct 2020 23:05:09

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 6'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:43', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'None (0)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:47', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'None (0)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:05:52', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'None (0)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:06:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'None (0)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:06:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'None (0)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:06:21', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'None (0)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:06:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered 'No (N)'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-13T19:06:53', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce97bc0b-e28e-4165-bd6c-6226a2896983' User entered '13 Oct 2020 19:06'	System	13 Oct 2020 23:06:56
	System	13 Oct 2020 23:06:56

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	08 Oct 2020 16:45:43
User entered 'Day 7'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'None (0)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'None (0)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:21', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'None (0)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:23', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'None (0)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'None (0)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:29', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'None (0)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

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)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:33', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered 'No (N)'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-10-14T19:03:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1d80a01f-82ea-44e8-a3c7-a0fe0395f2cf' User entered '14 Oct 2020 19:03'	System	14 Oct 2020 23:03:39
	System	14 Oct 2020 23:03:39

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 16:45:43

US3482267

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:49:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 16:45:43

US3482267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:27:16

US3482267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:27:16

US3482267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:27:16

US3482267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User closed query 'Per DM CLR: Comment = SWITCHED ALLEGRA TO ZYRTEC VISITED CARDIOLOGIST AND EVERYTHING WAS FINE. Review if this medication (i.e. ALLEGRA) should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:59:27
Query 'Per DM CLR: Comment = SWITCHED ALLEGRA TO ZYRTEC VISITED CARDIOLOGIST AND EVERYTHING WAS FINE. Review if this medication (i.e. ALLEGRA) should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' answered with 'updated concomitant medication page' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:56:40
User entered "'SWITCHED allergy medicine TO ZYRTEC VISITED CARDIOLOGIST AND EVERYTHING WAS FINE'" reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 14:56:23
User opened query 'Per DM CLR: Comment = SWITCHED ALLEGRA TO ZYRTEC VISITED CARDIOLOGIST AND EVERYTHING WAS FINE. Review if this medication (i.e. ALLEGRA) should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 07:11:08
User entered "'switched Allegra to Zyrtec visited cardiologist and everything was fine'" reason for change: New Information	(b) (4), (b) (6)	16 Oct 2020 17:52:11
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 21:27:16

US3482267

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:27:20

US3482267

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'I'	System	15 Oct 2020 21:27:20

US3482267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:16:34

US3482267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:16:34

US3482267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:16:34

US3482267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:58:42
User entered 'experiencing tremors, condition diagnosed prior to study enrollment, however getting worse in left hands; noticed last week and started taking clonazepam (originally taking medicine as needed)'	(b) (4), (b) (6)	22 Oct 2020 18:16:34

US3482267

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:16:39

US3482267

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'I'	System	22 Oct 2020 18:16:39

US3482267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:17:18

US3482267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:17:18

US3482267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:17:18

US3482267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:17:18

US3482267

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:17:21

US3482267

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'I'	System	02 Nov 2020 15:17:21

US3482267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:35

US3482267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:35

US3482267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:35

US3482267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'VISIT3'	System	05 Nov 2020 16:37:35

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered empty.	System	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered empty.	System	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered empty.	System	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered empty.	System	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered empty.	System	05 Nov 2020 16:37:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39

US3482267

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:42

US3482267

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:42

US3482267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:51

US3482267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:51

US3482267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered '11:15'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:51

US3482267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered '5 Nov 2020 11:15'	System	05 Nov 2020 16:37:51

US3482267

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	13 Feb 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:37:53

US3482267

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'I'	System	05 Nov 2020 16:37:53

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 64'	System	10 Sep 2020 14:57:37

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-10T08:14:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '90a2bcf6-5ec3-4e2f-83f1-660f90c8498d' User entered 'No (N)'	System	10 Nov 2020 13:15:16
	System	10 Nov 2020 13:15:16

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-10T08:14:39', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '90a2bcf6-5ec3-4e2f-83f1-660f90c8498d' User entered 'No (N)'	System	10 Nov 2020 13:15:16
	System	10 Nov 2020 13:15:16

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-10T08:15:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '90a2bcf6-5ec3-4e2f-83f1-660f90c8498d' User entered '10 Nov 2020 08:15:11'	System	10 Nov 2020 13:15:16
	System	10 Nov 2020 13:15:16

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 14:57:37

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered 'Day 71'	System	10 Sep 2020 14:57:37

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-17T01:42:41', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3e36d4f6-edd5-4f28-8bf1-f514cffe988f'	System	17 Nov 2020 06:43:25
User entered 'No (N)'	System	17 Nov 2020 06:43:25

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-17T01:42:53', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3e36d4f6-edd5-4f28-8bf1-f514cffe988f'	System	17 Nov 2020 06:43:25
User entered 'No (N)'	System	17 Nov 2020 06:43:25

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-17T01:43:19', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '3e36d4f6-edd5-4f28-8bf1-f514cffe988f' User entered '17 Nov 2020 01:43:19'	System	17 Nov 2020 06:43:25
	System	17 Nov 2020 06:43:25

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 14:57:37

US3482267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:49:26
Data entry locked.	System	10 Sep 2020 14:57:37
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 14:57:37

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-21T09:40:40', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2ccbc5f2-c84d-4f70-9ab4-ef5be7c46f37' User entered 'No (N)'	System	21 Nov 2020 14:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-21T09:40:51', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2ccbc5f2-c84d-4f70-9ab4-ef5be7c46f37' User entered 'No (N)'	System	21 Nov 2020 14:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-21T09:41:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2ccbc5f2-c84d-4f70-9ab4-ef5be7c46f37' User entered '21 Nov 2020 09:41:10'	System	21 Nov 2020 14:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-28T08:18:18', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1304607f-e073-4057-bbc8-dd00a2137372' User entered 'Yes (Y)'	System	28 Nov 2020 13:20:04
	System	28 Nov 2020 13:20:04

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-28T08:18:25', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1304607f-e073-4057-bbc8-dd00a2137372'	System	28 Nov 2020 13:20:04
User entered 'No (N)'	System	28 Nov 2020 13:20:04

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-28T08:18:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1304607f-e073-4057-bbc8-dd00a2137372'	System	28 Nov 2020 13:20:04
User entered 'No (N)'	System	28 Nov 2020 13:20:04

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-28T08:19:05', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1304607f-e073-4057-bbc8-dd00a2137372' User entered 'No (N)'	System	28 Nov 2020 13:20:04
	System	28 Nov 2020 13:20:04

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-11-28T08:20:01', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '1304607f-e073-4057-bbc8-dd00a2137372' User entered '28 Nov 2020 08:20:01'	System	28 Nov 2020 13:20:04
	System	28 Nov 2020 13:20:04

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-05T00:55:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '709a83a2-94a8-4830-965c-7f181d90f248' User entered 'No (N)'	System	05 Dec 2020 05:56:11
	System	05 Dec 2020 05:56:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-05T00:55:56', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '709a83a2-94a8-4830-965c-7f181d90f248' User entered 'No (N)'	System	05 Dec 2020 05:56:11
	System	05 Dec 2020 05:56:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-05T00:56:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '709a83a2-94a8-4830-965c-7f181d90f248' User entered '05 Dec 2020 00:56:08'	System	05 Dec 2020 05:56:11
	System	05 Dec 2020 05:56:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T09:57:28', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered 'Yes (Y)'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T09:57:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered 'No (N)'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:07:03', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered 'Yes (Y)'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '1'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:05:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '0'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Please 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:07:31', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e'	System	12 Dec 2020 15:08:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:07:41', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered 'No (N)'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-12T10:08:43', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '104fa9a7-084b-448e-983d-af164e53587e' User entered '12 Dec 2020 10:08:43'	System	12 Dec 2020 15:08:55
	System	12 Dec 2020 15:08:55

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:36:45', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered 'Yes (Y)'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:36:57', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered 'No (N)'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:37:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered 'Yes (Y)'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '1'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '1'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1'	System	19 Dec 2020 12:41:12
User entered '1'	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '1'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:11', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '0'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Please 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:27', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1'	System	19 Dec 2020 12:41:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:38:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered 'Yes (Y)'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Please 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:39:09', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1'	System	19 Dec 2020 12:41:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-19T07:41:02', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c8c2998c-4f15-40fa-8d2c-20af29915fc1' User entered '19 Dec 2020 07:41:02'	System	19 Dec 2020 12:41:12
	System	19 Dec 2020 12:41:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:08:50', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered 'Yes (Y)'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered 'No (N)'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:32', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered 'Yes (Y)'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '1'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '1'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '1'	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:09:59', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '0'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Please 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:10:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba'	System	26 Dec 2020 18:10:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:10:17', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered 'Yes (Y)'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Please 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:10:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba'	System	26 Dec 2020 18:10:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2020-12-26T13:10:46', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'e0cf588d-bcba-4764-8fb1-11eb60e053ba' User entered '26 Dec 2020 13:10:46'	System	26 Dec 2020 18:10:57
	System	26 Dec 2020 18:10:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-02T07:42:38', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a7f02fb5-a2bf-4572-9681-c0f2a9f61fbd' User entered 'No (N)'	System	02 Jan 2021 12:43:01

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-02T07:42:44', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a7f02fb5-a2bf-4572-9681-c0f2a9f61fbd' User entered 'No (N)'	System	02 Jan 2021 12:43:01

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-02T07:42:58', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a7f02fb5-a2bf-4572-9681-c0f2a9f61fbd' User entered '02 Jan 2021 07:42:58'	System	02 Jan 2021 12:43:01

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-09T06:30:08', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '19d60298-1d20-4036-87cc-2be7ee440021' User entered 'No (N)'	System	14 Jan 2021 00:14:34
	System	14 Jan 2021 00:14:34

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-09T06:30:15', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '19d60298-1d20-4036-87cc-2be7ee440021'	System	14 Jan 2021 00:14:34
User entered 'No (N)'	System	14 Jan 2021 00:14:34

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-09T06:30:30', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '19d60298-1d20-4036-87cc-2be7ee440021' User entered '09 Jan 2021 06:30:30'	System	14 Jan 2021 00:14:34

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-17T15:45:45', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a33415d7-23f4-417c-800a-ac1f5d20eb47'	System	17 Jan 2021 20:46:06
User entered 'No (N)'	System	17 Jan 2021 20:46:06

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-17T15:45:54', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a33415d7-23f4-417c-800a-ac1f5d20eb47'	System	17 Jan 2021 20:46:06
User entered 'No (N)'	System	17 Jan 2021 20:46:06

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-17T15:46:03', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'a33415d7-23f4-417c-800a-ac1f5d20eb47' User entered '17 Jan 2021 15:46:03'	System	17 Jan 2021 20:46:06
	System	17 Jan 2021 20:46:06

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-23T11:32:16', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '8ce263f3-0ae5-4a43-9487-ecdad7c9236d' User entered 'No (N)'	System	27 Jan 2021 22:21:50
	System	27 Jan 2021 22:21:50

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-23T11:32:26', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '8ce263f3-0ae5-4a43-9487-ecdad7c9236d'	System	27 Jan 2021 22:21:50
User entered 'No (N)'	System	27 Jan 2021 22:21:50

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-23T11:32:34', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '8ce263f3-0ae5-4a43-9487-eccdad7c9236d' User entered '23 Jan 2021 11:32:34'	System	27 Jan 2021 22:21:50
	System	27 Jan 2021 22:21:50

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-30T07:57:49', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b1d02cb5-6769-4a31-b55a-56b46df6142f' User entered 'No (N)'	System	30 Jan 2021 12:58:25
	System	30 Jan 2021 12:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-30T07:58:02', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b1d02cb5-6769-4a31-b55a-56b46df6142f' User entered 'No (N)'	System	30 Jan 2021 12:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-01-30T07:58:21', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b1d02cb5-6769-4a31-b55a-56b46df6142f' User entered '30 Jan 2021 07:58:21'	System	30 Jan 2021 12:58:25
	System	30 Jan 2021 12:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-06T00:44:28', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dc654d7c-1f33-4207-8ec3-88061da63077' User entered 'No (N)'	System	06 Feb 2021 05:45:08
	System	06 Feb 2021 05:45:08

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-06T00:44:34', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dc654d7c-1f33-4207-8ec3-88061da63077'	System	06 Feb 2021 05:45:08
User entered 'No (N)'	System	06 Feb 2021 05:45:08

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-06T00:44:41', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'dc654d7c-1f33-4207-8ec3-88061da63077' User entered '06 Feb 2021 00:44:41'	System	06 Feb 2021 05:45:08
	System	06 Feb 2021 05:45:08

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-13T01:27:54', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2ed994d5-bf0d-4a91-91d6-1e4ed5760119' User entered 'No (N)'	System	13 Feb 2021 06:28:14
	System	13 Feb 2021 06:28:14

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-13T01:28:03', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2ed994d5-bf0d-4a91-91d6-1e4ed5760119' User entered 'No (N)'	System	13 Feb 2021 06:28:14
	System	13 Feb 2021 06:28:14

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-13T01:28:10', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '2ed994d5-bf0d-4a91-91d6-1e4ed5760119' User entered '13 Feb 2021 01:28:10'	System	13 Feb 2021 06:28:14
	System	13 Feb 2021 06:28:14

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-20T07:52:07', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '533aeccd-8e97-4793-a4bf-efc1e300d6d9' User entered 'No (N)'	System	20 Feb 2021 12:52:49
	System	20 Feb 2021 12:52:49

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-20T07:52:22', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '533aeccd-8e97-4793-a4bf-efc1e300d6d9' User entered 'No (N)'	System	20 Feb 2021 12:52:49
	System	20 Feb 2021 12:52:49

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-20T07:52:42', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '533aeccd-8e97-4793-a4bf-efc1e300d6d9' User entered '20 Feb 2021 07:52:42'	System	20 Feb 2021 12:52:49
	System	20 Feb 2021 12:52:49

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-27T11:18:36-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '37db0d97-d2ad-4b2b-b41d-9a084579d6ed' User entered 'No (N)'	System	27 Feb 2021 16:19:11
	System	27 Feb 2021 16:19:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-27T11:18:49-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '37db0d97-d2ad-4b2b-b41d-9a084579d6ed' User entered 'No (N)'	System	27 Feb 2021 16:19:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-27T11:19:08-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '37db0d97-d2ad-4b2b-b41d-9a084579d6ed' User entered '27 Feb 2021 16:19:08'	System	27 Feb 2021 16:19:11
	System	27 Feb 2021 16:19:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-06T11:31:29-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6ec2d4d4-4e82-4e44-8a6f-8dca9eb89d79'	System	09 Mar 2021 04:54:06
User entered 'No (N)'	System	09 Mar 2021 04:54:06

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-06T11:32:14-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6ec2d4d4-4e82-4e44-8a6f-8dca9eb89d79'	System	09 Mar 2021 04:54:06
User entered 'No (N)'	System	09 Mar 2021 04:54:06

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-06T11:33:11-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '6ec2d4d4-4e82-4e44-8a6f-8dca9eb89d79' User entered '06 Mar 2021 11:33:11'	System	09 Mar 2021 04:54:06
	System	09 Mar 2021 04:54:06

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-13T16:53:55-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '652326e3-e690-4dbb-ba42-76b3143a5fb9' User entered 'No (N)'	System	13 Mar 2021 21:54:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-13T16:54:03-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '652326e3-e690-4dbb-ba42-76b3143a5fb9' User entered 'No (N)'	System	13 Mar 2021 21:54:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-13T16:54:10-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '652326e3-e690-4dbb-ba42-76b3143a5fb9' User entered '13 Mar 2021 16:54:10'	System	13 Mar 2021 21:54:12
	System	13 Mar 2021 21:54:12

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-20T01:51:09-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b06105f6-9f96-4ffa-8b01-a18104d94c15'	System	20 Mar 2021 05:53:19
User entered 'No (N)'	System	20 Mar 2021 05:53:19

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-20T01:51:33-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b06105f6-9f96-4ffa-8b01-a18104d94c15'	System	20 Mar 2021 05:53:19
User entered 'No (N)'	System	20 Mar 2021 05:53:19

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-20T01:51:41-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'b06105f6-9f96-4ffa-8b01-a18104d94c15' User entered '20 Mar 2021 01:51:41'	System	20 Mar 2021 05:53:19
	System	20 Mar 2021 05:53:19

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-27T22:43:59-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce6c5443-8a4f-4eb1-9eda-ac6d260dc4f5'	System	01 Apr 2021 11:46:53
User entered 'No (N)'	System	01 Apr 2021 11:46:53

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-27T22:44:04-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce6c5443-8a4f-4eb1-9eda-ac6d260dc4f5'	System	01 Apr 2021 11:46:53
User entered 'No (N)'	System	01 Apr 2021 11:46:53

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-03-27T22:44:10-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'ce6c5443-8a4f-4eb1-9eda-ac6d260dc4f5'	System	01 Apr 2021 11:46:53
User entered '27 Mar 2021 22:44:10'	System	01 Apr 2021 11:46:53

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-03T12:20:42-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '23eca706-9a66-4515-85f9-4a5f7177a1f9'	System	03 Apr 2021 16:21:56
User entered 'Yes (Y)'	System	03 Apr 2021 16:21:56

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-03T12:20:47-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '23eca706-9a66-4515-85f9-4a5f7177a1f9'	System	03 Apr 2021 16:21:56
User entered 'No (N)'	System	03 Apr 2021 16:21:56

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-03T12:20:54-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '23eca706-9a66-4515-85f9-4a5f7177a1f9'	System	03 Apr 2021 16:21:56
User entered 'No (N)'	System	03 Apr 2021 16:21:56

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-03T12:21:03-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '23eca706-9a66-4515-85f9-4a5f7177a1f9'	System	03 Apr 2021 16:21:56
User entered 'Yes (Y)'	System	03 Apr 2021 16:21:56

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Please 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-03T12:21:14-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '23eca706-9a66-4515-85f9-4a5f7177a1f9'	System	03 Apr 2021 16:21:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 16:21:56

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-03T12:21:44-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '23eca706-9a66-4515-85f9-4a5f7177a1f9' User entered '03 Apr 2021 12:21:44'	System	03 Apr 2021 16:21:56
	System	03 Apr 2021 16:21:56

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-11T23:19:44-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '0daf54d6-0195-4976-957c-4ec2fb7c9a4f'	System	12 Apr 2021 03:19:59
User entered 'No (N)'	System	12 Apr 2021 03:19:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-11T23:19:49-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '0daf54d6-0195-4976-957c-4ec2fb7c9a4f'	System	12 Apr 2021 03:19:59
User entered 'No (N)'	System	12 Apr 2021 03:19:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-11T23:19:56-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '0daf54d6-0195-4976-957c-4ec2fb7c9a4f'	System	12 Apr 2021 03:19:59
User entered '11 Apr 2021 23:19:56'	System	12 Apr 2021 03:19:59

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-17T12:29:59-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '35c8ed17-035c-497c-84d2-8dc1fc81e311' User entered 'No (N)'	System	26 Apr 2021 16:01:11
	System	26 Apr 2021 16:01:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-17T12:30:08-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '35c8ed17-035c-497c-84d2-8dc1fc81e311'	System	26 Apr 2021 16:01:11
User entered 'No (N)'	System	26 Apr 2021 16:01:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-17T12:30:14-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '35c8ed17-035c-497c-84d2-8dc1fc81e311' User entered '17 Apr 2021 12:30:14'	System	26 Apr 2021 16:01:11
	System	26 Apr 2021 16:01:11

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-26T12:00:40-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c81e69d6-ab0d-47a2-a2a4-431564d9d162'	System	26 Apr 2021 16:02:57
User entered 'No (N)'	System	26 Apr 2021 16:02:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-26T12:00:47-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c81e69d6-ab0d-47a2-a2a4-431564d9d162'	System	26 Apr 2021 16:02:57
User entered 'No (N)'	System	26 Apr 2021 16:02:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-04-26T12:00:56-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: 'c81e69d6-ab0d-47a2-a2a4-431564d9d162'	System	26 Apr 2021 16:02:57
User entered '26 Apr 2021 12:00:56'	System	26 Apr 2021 16:02:57

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-05-01T07:20:22-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '35ce1005-18b5-4589-bf75-1541300da980'	System	03 May 2021 09:48:50
User entered 'No (N)'	System	03 May 2021 09:48:50

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

Have you been exposed to someone with 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 (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-05-01T07:20:28-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '35ce1005-18b5-4589-bf75-1541300da980'	System	03 May 2021 09:48:50
User entered 'No (N)'	System	03 May 2021 09:48:50

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-05-01T07:20:33-04:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '35ce1005-18b5-4589-bf75-1541300da980'	System	03 May 2021 09:48:50
User entered '01 May 2021 07:20:33'	System	03 May 2021 09:48:50

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 06:58:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 06:58:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 06:58:25

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Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 06:58:25

US3482267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:49:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:58:25
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 06:58:25

US3482267

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:49:35

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 13:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-27T11:19:22-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4381c07a-5ba9-4184-ad10-f9ea5058982b' User entered 'No (N)'	System	06 Mar 2021 16:30:30
	System	06 Mar 2021 16:30:30

US3482267

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:49:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C75D5DEC-6FE7-4A4B-BE2C-4C7E7BCF7297)', Time: '2021-02-27T11:19:38-05:00', User OID: 'PatientReportedOutcome (US3482267)', ODM File OID: '4381c07a-5ba9-4184-ad10-f9ea5058982b' User entered '27 Feb 2021 16:19:38'	System	06 Mar 2021 16:30:30
	System	06 Mar 2021 16:30:30

US3482267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:29:48

US3482267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:29:48

US3482267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:29:48

US3482267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:29:48

US3482267

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 17:29:55

US3482267

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:41:39
User entered 'I'	System	04 Dec 2020 17:29:55

US3482267

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:49:59

US3482267

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:49:59

US3482267

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:49:59

US3482267

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:49:59

US3482267

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:50:04

US3482267

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User entered 'I'	System	06 Jan 2021 20:50:04

US3482267

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:31:31

US3482267

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:31:31

US3482267

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:31:31

US3482267

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:31:31

US3482267

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:31:37

US3482267

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User entered 'I'	System	05 Feb 2021 18:31:37

US3482267

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:51:28

US3482267

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:51:28

US3482267

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:51:28

US3482267

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:51:28

US3482267

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:51:32

US3482267

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:03:07
User entered 'I'	System	08 Mar 2021 20:51:32

US3482267

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:17:27

US3482267

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 16:17:27

US3482267

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 16:17:27

US3482267

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered 'VISIT4'	System	24 Mar 2021 16:17:27

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User closed query ' Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 24Mar2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:36:12
Query ' Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 24Mar2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. ' answered with 'Data entered' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:50:42
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
User opened query ' Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 24Mar2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'No (N)'	(b) (4) Michelle Wiles (b) (4)	31 Mar 2021 23:30:36

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
User entered '11:39' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered '24 Mar 2021 11:39'	System	07 Apr 2021 13:50:30
User entered empty.	System	31 Mar 2021 23:30:36

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered '89' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered 'bpm'	System	07 Apr 2021 13:50:30
User entered empty.	System	31 Mar 2021 23:30:36

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered 'breaths/min'	System	07 Apr 2021 13:50:30
User entered empty.	System	31 Mar 2021 23:30:36

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered 'mmHg'	System	07 Apr 2021 13:50:30
User entered empty.	System	31 Mar 2021 23:30:36

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User entered '63' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:50:30
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered empty.	Michelle Wiles (b) (4)	31 Mar 2021 23:30:36
	(b) (4)	

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered 'mmHg'	System	07 Apr 2021 13:50:30
User entered empty.	System	31 Mar 2021 23:30:36

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23

US3482267

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23

US3482267

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:17:34

US3482267

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 16:17:34

US3482267

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:17:44

US3482267

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 16:17:44

US3482267

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered '11:48'	(b) (4), (b) (6)	24 Mar 2021 16:17:44

US3482267

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered '24 Mar 2021 11:48'	System	24 Mar 2021 16:17:44

US3482267

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 16:17:50

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:41:23
User entered '1'	System	24 Mar 2021 16:17:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:49:35

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '12 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:07:51

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:49:35

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '11:04'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:07:51

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:49:35

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:39
User entered '12 Dec 2020 11:04'	System	15 Dec 2020 18:07:51

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:49:35

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Safety Call (Safety Call)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:07:51

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:49:35

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:39
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:07:51

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 1 (Day 1)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '10 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User closed query 'Per CDM: Please check from log lines 1-4. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 14:54:26
Query 'Per CDM: Please check from log lines 1-4. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' answered with 'corrected' (Site from DM).	Hollie Macenczak (b) (4)	15 Jan 2021 14:53:14
User entered '0' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User opened query 'Per CDM: Please check from log lines 1-4. Assessment Not Done is checked yet data is present. Please reconcile the data and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:37:23
User entered '1'	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	15 Jan 2021 14:53:03
User entered empty.	System	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:08:55

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 2 (Day 2)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '11 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered '1'	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	15 Jan 2021 14:53:03
User entered empty.	System	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:03

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 3 (Day 3)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '12 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered '1'	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	15 Jan 2021 14:53:03
User entered empty.	System	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 4 (Day 4)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '13 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered '1'	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	15 Jan 2021 14:53:03
User entered empty.	System	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:10:26
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 14:53:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:11:28

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 5 (Day 5)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '98'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '97' F	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:14:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 6 (Day 6)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '15 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '94'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (6)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '97.8' F	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 7 (Day 7)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '16 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '95'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '97.5' F	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (7)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	16 Dec 2020 23:25:00

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 8 (Day 8)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '17 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '83'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	18 Dec 2020 01:08:50

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '96.9' F	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	18 Dec 2020 01:08:50

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Day 9 (Day 9)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '18 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User entered '%'	System	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Moderate (Moderate)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Mild (Mild)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:49:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:48
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'None (None)'	(b) (4) Hollie Macenczak (b) (4)	22 Dec 2020 02:17:14

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

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 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

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 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
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	22 Dec 2020 02:19:51
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:19:51
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 18:15:30
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

[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 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

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Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:15:30

US3482267

Folder: Covid-19 Assessment 12 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:49:35

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:52:15
User entered '0'	System	22 Dec 2020 02:19:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered '16 Dec 2020'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:21:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 10:38:47
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	17 Dec 2020 15:43:46
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:31:08
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:21:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 10:38:53
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	17 Dec 2020 15:44:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:31:08
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:21:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 10:38:58
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	17 Dec 2020 15:44:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:31:08
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:21:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 10:39:05
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	17 Dec 2020 15:44:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:31:08
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:21:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 10:39:12
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	17 Dec 2020 15:44:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:31:08
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:49:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:49:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Hollie Macenczak (b) (4)	22 Dec 2020 02:21:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 10:39:18
Query 'Data is required. Please complete.' answered with 'not yet due' (Site from System).	Amy Anderson (b) (4)	17 Dec 2020 15:44:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 23:31:08
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	16 Dec 2020 23:31:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:05:04

US3482267

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:05:04

US3482267

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Clinic (Clinic)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:05:04

US3482267

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User entered 'SICKD1'	System	15 Dec 2020 18:05:04

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '15:02'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User entered '14 Dec 2020 15:02'	System	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08
DataPoint set to visible.	System	15 Dec 2020 18:05:04

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered missing code ND - Not Done.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08
DataPoint set to visible.	System	15 Dec 2020 18:05:04

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '98.4' F	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Oral (Oral)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '97'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User entered 'bpm'	System	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '20'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User entered 'breaths/min'	System	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '162'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User entered 'mmHg'	System	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '75'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User entered 'mmHg'	System	15 Dec 2020 18:06:08

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38

US3482267

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38

US3482267

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:15

US3482267

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:15

US3482267

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:49:35

[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 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:21

US3482267

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:49:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:04:38
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '14 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 18:06:21

US3482267

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

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:57

US3482267

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

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:57

US3482267

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

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Clinic (Clinic)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:57

US3482267

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

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 16:39:57

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:50
Signature has been broken.	(b) (4)	
	Michele McCullough	23 Apr 2021 17:45:26
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	Michele McCullough	23 Apr 2021 17:45:26
	(b) (4)	
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:55:33
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'updated' (Site from DM).	Mari Hart (b) (4)	08 Apr 2021 18:34:49
	(b) (4)	
Signature has been broken.	Mari Hart (b) (4)	08 Apr 2021 18:34:21
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mari Hart (b) (4)	08 Apr 2021 18:34:21
	(b) (4)	
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 20:17:07

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
	(b) (4)	
User entered '24 Dec 2020'	Michelle Wiles (b) (4)	14 Jan 2021 16:42:18
	(b) (4)	

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User closed query 'Per CDM: Under what version of the Protocol was the Participant unblinded? is recorded as A6 or later. However, Subject Unblinded under A5 and Discontinued from Study is selected. Please review and reconcile. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Nadine Rouphael (b) (4)	23 Apr 2021 15:27:29 17 Apr 2021 03:11:30
Query 'Per CDM: Under what version of the Protocol was the Participant unblinded? is recorded as A6 or later. However, Subject Unblinded under A5 and Discontinued from Study is selected. Please review and reconcile. ' answered with 'updated' (Site from DM).	Mari Hart (b) (4) (b) (4)	12 Apr 2021 22:33:45
Signature has been broken.	Mari Hart (b) (4) (b) (4)	12 Apr 2021 22:33:27
User entered '0' reason for change: Per Query Resolution	Mari Hart (b) (4) (b) (4)	12 Apr 2021 22:33:27
User opened query 'Per CDM: Under what version of the Protocol was the Participant unblinded? is recorded as A6 or later. However, Subject Unblinded under A5 and Discontinued from Study is selected. Please review and reconcile. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Nadine Rouphael (b) (4)	12 Apr 2021 20:56:52 12 Apr 2021 16:19:30
User entered '1'	Mari Hart (b) (4) (b) (4)	08 Apr 2021 18:34:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:55:34

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4)	
	System	14 Jan 2021 16:42:24
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	14 Jan 2021 16:42:24
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	14 Jan 2021 16:42:18
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	14 Jan 2021 16:42:18
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	28 Apr 2021 18:20:50
User closed query 'Per CDM: Per IRT, subject was unblinded under A6. Please update field and add date of updated informed consent per sponsor guidance document. Else, clarify the discrepancy.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 12:58:11
Query 'Per CDM: Per IRT, subject was unblinded under A6. Please update field and add date of updated informed consent per sponsor guidance document. Else, clarify the discrepancy.' answered with 'updated' (Site from DM).	Michele McCullough (b) (4)	23 Apr 2021 17:45:44
Signature has been broken.	Michele McCullough (b) (4)	23 Apr 2021 17:45:26
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Per Query Resolution	Michele McCullough (b) (4)	23 Apr 2021 17:45:26
User opened query 'Per CDM: Per IRT, subject was unblinded under A6. Please update field and add date of updated informed consent per sponsor guidance document. Else, clarify the discrepancy.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 15:53:48
User signature succeeded.	Nadine Rouphael (b) (4)	17 Apr 2021 03:11:30
Signature has been broken.	(b) (4) Mari Hart (b) (4)	12 Apr 2021 22:33:27
User entered 'Amendment 5 (Amendment 5)' reason for change: Per Query Resolution	(b) (4) Mari Hart (b) (4)	12 Apr 2021 22:33:27
User closed query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:55:40
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
Query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update.' answered with 'updated' (Site from DM).	Mari Hart (b) (4) (b) (4)	09 Apr 2021 16:36:34
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Mari Hart (b) (4) (b) (4)	09 Apr 2021 16:36:28

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User opened query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update.' (Site from DM). User entered 'Amendment 5 (Amendment 5)'	(b) (4), (b) (6)	09 Apr 2021 07:13:54
Amendment Manager inserted this DataPoint.	Mari Hart (b) (4) (b) (4) System	08 Apr 2021 18:34:21 06 Mar 2021 14:55:34

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:42:18

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Placebo (Placebo)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:42:18

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:18:05
User entered 'Placebo (Placebo)'	Michelle Wiles (b) (4)	14 Jan 2021 16:42:18
	(b) (4)	

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:18:05
User entered 'Placebo (Placebo)' reason for change:	Michelle Wiles (b) (4)	14 Jan 2021 16:42:24
Data Entry Error	(b) (4)	
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:42:18

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:42:18

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User entered '1'	System	14 Jan 2021 16:42:24
User entered empty.	System	14 Jan 2021 16:42:18

US3482267

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

Form: Unblinding

Generated On: 09 Jun 2021 17:49:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:15
User entered '1'	System	14 Jan 2021 16:42:24
User entered empty.	System	14 Jan 2021 16:42:18

US3482267

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered empty.	System	14 Jan 2021 16:45:39
DataPoint set to visible.	System	14 Jan 2021 16:42:24

US3482267

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered empty.	System	14 Jan 2021 16:45:39
DataPoint set to visible.	System	14 Jan 2021 16:42:24

US3482267

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User accepted default value 'Pre-Dose (PREDOSE)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '12:17'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '13 Jan 2021 12:17'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '98.4' F	Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '88'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'bpm'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '20'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'breaths/min'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '121'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '63'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	14 Jan 2021 16:45:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered missing code ND - Not Done.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:49:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered empty.	System	14 Jan 2021 16:45:39
DataPoint set to visible.	System	14 Jan 2021 16:42:24

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User accepted default value 'Post-Dose (POSTDOSE)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13:35'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '13 Jan 2021 13:35'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '98.8' F	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Oral (Oral)'	(b) (4) Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '81'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'bpm'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '18'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'breaths/min'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '128'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '64'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	14 Jan 2021 16:45:39

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:43:15

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:43:15

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mRNA-1273'	System	14 Jan 2021 16:46:30
DataPoint set to visible.	System	14 Jan 2021 16:42:24

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	System	14 Jan 2021 16:46:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Michelle Wiles (b) (4)	14 Jan 2021 16:46:37
User entered ' Jan 2021' (non-conformant).	(b) (4)	
	System	14 Jan 2021 16:46:30
	Michelle Wiles (b) (4)	14 Jan 2021 16:46:30
	(b) (4)	

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13:04'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '13 Jan 2021 13:04'	System	14 Jan 2021 16:46:37
User entered ' 13 Jan 2021 13:04' (non-conformant).	System	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'ONCE'	System	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 16:46:30

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:43:54

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:43:54

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '12:06'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:43:54

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '13 Jan 2021 12:06'	System	14 Jan 2021 16:43:54

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:44:04

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '13 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:44:04

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '12:08'	(b) (4) Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:44:04

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:49:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '13 Jan 2021 12:08'	System	14 Jan 2021 16:44:04

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:44:08

US3482267

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '1'	System	14 Jan 2021 16:44:08

US3482267

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 14:00:38

US3482267

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '20 Jan 2021'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 14:00:38

US3482267

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 14:00:38

US3482267

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 14:00:38

US3482267

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) Michelle Wiles (b) (4)	22 Jan 2021 14:00:46

US3482267

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'I'	System	22 Jan 2021 14:00:46

US3482267

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '1'	System	22 Jan 2021 14:00:46
DataPoint set to visible.	System	22 Jan 2021 14:00:46

US3482267

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:14

US3482267

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:14

US3482267

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:14

US3482267

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'OLD29'	System	10 Feb 2021 17:01:14

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '11:29'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '10 Feb 2021 11:29'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '92'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'bpm'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'breaths/min'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '123'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '69'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '12:35'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '10 Feb 2021 12:35'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '95'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'bpm'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'breaths/min'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '123' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:19:21
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Feb 2021 17:49:46
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	10 Feb 2021 17:49:46
User entered '126' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 17:49:46
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Feb 2021 17:49:24
User entered '6'	(b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	(b) (4)	10 Feb 2021 17:49:46
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 17:49:46
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	10 Feb 2021 17:49:24
User entered '66'	(b) (4), (b) (6)	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	10 Feb 2021 17:49:24

US3482267

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:24

US3482267

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:24

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mRNA-1273'	System	10 Feb 2021 17:01:41
DataPoint set to visible.	System	22 Jan 2021 14:00:46

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '12:01' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:54
User entered '12:03'	(b) (4), (b) (6)	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '10 Feb 2021 12:01'	System	11 Feb 2021 16:18:54
User entered '10 Feb 2021 12:03'	System	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'ONCE'	System	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:49:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 17:01:41

US3482267

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:01:47

US3482267

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'I'	System	10 Feb 2021 17:01:47

US3482267

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:52

US3482267

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:52

US3482267

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:52

US3482267

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:49:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:52

US3482267

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:33:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:53:56

US3482267

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:49:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'I'	System	19 Feb 2021 15:53:56

US3482267

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:03

US3482267

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:03

US3482267

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:18:03

US3482267

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:49:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'OLD57'	System	24 Mar 2021 16:18:03

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '11:39'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '24 Mar 2021 11:39'	System	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '89'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'bpm'	System	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'breaths/min'	System	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '136'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '63'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered 'mmHg'	System	24 Mar 2021 16:19:18

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00

US3482267

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:49:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00

US3482267

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:24

US3482267

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:49:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:24

US3482267

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:37

US3482267

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:37

US3482267

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User signature succeeded.	Nadine Rouphael (b) (4)	01 Apr 2021 23:32:45
User entered '11:48'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:19:37

US3482267

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:49:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:54:00
User entered '24 Mar 2021 11:48'	System	24 Mar 2021 16:19:37

US3482267

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:49:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:07
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:28
User entered 'Yes (Y)'	Easton Beshears (b) (4) (b) (4)	15 Sep 2020 18:33:05

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site bruising, LLT: Injection site bruising - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 06:32:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 06:32:52
Data point term sent to Coder	System	15 Sep 2020 18:37:28
User entered 'Bruised arm after injection'	Easton Beshears (b) (4)	15 Sep 2020 18:36:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:25:35
User entered 'No (N)'	Easton Beshears (b) (4) (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '10:29'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User entered '10 Sep 2020 10:29'	System	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '10 Sep 2020'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '23:59' reason for change: Data Entry Error	System	15 Sep 2020 18:37:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Easton Beshears (b) (4)	15 Sep 2020 18:37:01
User entered 'un:un' (non-conformant).	(b) (4)	
	System	15 Sep 2020 18:36:33
	Easton Beshears (b) (4)	15 Sep 2020 18:36:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User entered '10 Sep 2020 23:59'	System	15 Sep 2020 18:37:01
User entered '10 Sep 2020 UN:UN' (non-conformant).	System	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 22:25:35
User entered 'Related (RELATED)'	Easton Beshears (b) (4)	15 Sep 2020 18:36:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:25:35
User entered 'Not Related (NOT RELATED)'	Easton Beshears (b) (4) (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'None (NONE)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'I'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User entered '0'	System	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27
User entered '1'	System	19 Jan 2021 22:25:35
User entered '0'	System	15 Sep 2020 18:36:33

US3482267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Vasovagal symptoms - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Oct 2020 18:23:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:23:28
Data point term sent to Coder	System	09 Oct 2020 18:21:59
User entered 'Vasovagal syndrome'	Easton Beshears (b) (4) (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '08 Oct 2020'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '12:56'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User entered '08 Oct 2020 12:56'	System	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '08 Oct 2020'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '14:30'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User entered '08 Oct 2020 14:30'	System	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 04:30:23
Query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you.	(b) (4), (b) (6)	24 Nov 2020 18:14:23
' answered with 'Updated' (Site from DM). User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:14:17
User opened query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:27:15
User entered 'Not Applicable (NOT APPLICABLE)'	Easton Beshears (b) (4) (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Related (RELATED)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'None (NONE)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'I'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Pt experienced a vasovagal episode 5-10 minutes after injection. See progress notes for details. Diastolic BP was < 60 and hence grade 3 per protocol.'	(b) (4) Easton Beshears (b) (4)	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User entered '0'	System	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32
User entered '1'	System	09 Oct 2020 18:21:37

US3482267

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 21:44:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 21:44:00
	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 17:22:57
Coding entries removed.	(b) (4), (b) (6)	10 Mar 2021 17:22:28
	(b) (4), (b) (6)	
User entered 'INTERMITTENT TREMORS' reason for change: New Information	(b) (4), (b) (6)	10 Mar 2021 17:22:28
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:11:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:11:45
	(b) (4)	
Data point term sent to Coder	System	08 Dec 2020 18:11:15
User entered 'Tremors'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:27:22
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:40:40
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'UPDATE 10MAR2021: PPT STATES TREMORS ARE INTERMITTENT BUT STILL ONGOING. NEW BASELINE ESTABLISHED.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:21:28
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 22:27:22
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	08 Dec 2020 18:10:52
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Dec 2020 18:10:52
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Dec 2020 18:10:29
User entered '1'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Per response, please consider updating the Indication of the medication to include this event.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Nadine Rouphael (b) (4)	15 Mar 2021 11:01:02 13 Mar 2021 03:24:42
Query 'Per CDM re-query: Per response, please consider updating the Indication of the medication to include this event.' answered with 'USED ONCE FOR THIS PURPOSE, NOT PER DOCTOR INSTRUCTION AND WITHOUT RELIEF. NOT MEDICALLY APPROPRIATE TO UPDATE INDICATION.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:21:37
User opened query 'Per CDM re-query: Per response, please consider updating the Indication of the medication to include this event.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:45:08
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE term. Please review and update the medication's indication to include the event. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:45:08
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE term. Please review and update the medication's indication to include the event. Otherwise, clarify.' answered with 'IS ON CLONAZEPAM AS NEEDED. TRIED A CLONAZEPAM AT TIME OF SYMPTOM ONSET IN OCTOBER TO SEE IF THIS IMPROVED HER SYMPTOMS. SEE ASSOCIATED NOTES IN NARRATIVE.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:23:49
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE term. Please review and update the medication's indication to include the event. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:12:28
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:29

US3482267

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'SUBJECT STATED THEY WERE EXPERIENCING TREMORS; WHICH SUBJECT BELIEVES IS ATTRIBUTED TO CONDITION [RESTLESS LEG SYNDROME] DIAGNOSED PRIOR TO STUDY ENROLLMENT. HOWEVER, SUBJECT STATES IT IS GETTING WORSE IN LEFT HANDS. SUBJECT NOTICED LAST WEEK [12OCT2020] AND STARTED TAKING CLONAZEPAM (ORIGINALLY TAKING MEDICINE AS NEEDED); TOOK CLONAZEPAM ONCE IN OCTOBER TO AID IN CONDITION.'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:22:06
reason for change: New Information		
User closed query 'Per DM CLR: Narrative = TOOK CLONAZEPAM ONCE LAST WEEK TO AID IN CONDITION. Please review and ensure that the ConMed indication is updated to include this AE so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:44:34
Query 'Per DM CLR: Narrative = TOOK CLONAZEPAM ONCE LAST WEEK TO AID IN CONDITION. Please review and ensure that the ConMed indication is updated to include this AE so there will be an appropriate match. Update eCRF as appropriate.' answered with 'CLONAZEPAM IS IN CON MEDS FOR ANXIETY. PPT DID A TRIAL OF THIS TO SEE IF IT ALSO HELPED HER TREMORS BUT DID NOT CONTINUE IT AS IT DID NOT HAVE A BENEFIT.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:25:04
User opened query 'Per DM CLR: Narrative = TOOK CLONAZEPAM ONCE LAST WEEK TO AID IN CONDITION. Please review and ensure that the ConMed indication is updated to include this AE so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:22:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject stated they were experiencing tremors; which subject believes is attributed to condition [restless leg syndrome] diagnosed prior to study enrollment. However, subject states it is getting worse in left hands. Subject noticed last week [12Oct2020] and started taking clonazepam (originally taking medicine as needed); took clonazepam once last week to aid in condition.'	(b) (4), (b) (6)	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:49:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 22:27:22
User entered '0'	System	08 Dec 2020 18:10:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial. 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)	16 Jan 2021 04:16:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash macular, LLT: Macular rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:16:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:16:59
Data point term sent to Coder	System	14 Jan 2021 20:00:53
Query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial. 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).	Hollie Macenczak (b) (4)	14 Jan 2021 20:00:33
Coding entries removed.	Hollie Macenczak (b) (4)	14 Jan 2021 20:00:26
User entered 'Macular, non-urticarial RASH on bilateral hands' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	14 Jan 2021 20:00:26
User opened query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) and location (eg, Injection site, etc) of RASH and if this is Urticarial or Non-Urticarial. 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)	29 Dec 2020 08:22:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 19:09:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 19:09:58
Data point term sent to Coder	System	15 Dec 2020 19:09:01
User entered 'Rash'	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

US3482267

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '30 Nov 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

US3482267

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User entered empty.	System	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 06:20:19
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'AE Resolved 20 Feb 2021. (b) (6) (b) (6) 08 Mar 2021' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 20:58:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:57:33
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:12:44
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '20 Feb 2021' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	08 Mar 2021 20:57:33
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User entered empty.	System	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	16 Feb 2021 15:26:12
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

US3482267

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'I'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:57:33
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 19:08:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 19:08:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:12
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 19:08:03
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User closed query 'Per DM CLR: SAE Narrative = REPORTS HAVING HAD SIMILAR RASH IN THE PAST RELATED TO HER CATS AT HOME. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	15 Mar 2021 11:01:50
	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
Query 'Per DM CLR: SAE Narrative = REPORTS HAVING HAD SIMILAR RASH IN THE PAST RELATED TO HER CATS AT HOME. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'Never had a clear diagnosis in the past whether this was allergic, or fungal, and it was unclear what other sites were affected. Had been treated with both antifungals and steroids previously. Because of this uncertainty and remote history of a similar event, it was not disclosed as potential "medical history" until the recurrence of similar. For this reason it was not judged too vague & not defined enough to enter into the Med Hx.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:53:37
User opened query 'Per DM CLR: SAE Narrative = REPORTS HAVING HAD SIMILAR RASH IN THE PAST RELATED TO HER CATS AT HOME. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:09:07
User entered 'Subject reports rash x2 weeks with start date of approximately 30NOV2020. Site provider examined subject during illness visit on 14DEC2020. Rash found to be erythematous/macular about 2-3cm in diameter over dorsal regions of bilateral hands. Has appointment scheduled with PCP. Reports having had similar rash in the past related to her cats at home.'	Hollie Macenczak (b) (4)	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User entered '0'	System	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47
User entered 'I'	System	15 Dec 2020 19:08:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:39:51
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:19
User entered		
'USA-US106-2020-mRNA-1273-P301000010'	System	22 Dec 2020 18:25:06
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:06
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 18:25:06
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:24:01
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 18:23:47

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:39:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 11:20:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 11:20:47
Data point term sent to Coder	System	22 Dec 2020 02:15:30
User entered 'acute pulmonary emboli'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:39:54
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:39:56
User entered 'No (N)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:39:57
User entered 'No (N)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:39:59
User entered '18 Dec 2020'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:40:04
User entered empty.	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
DataPoint Un-verified.	Lauren Hewitt (b) (4)	08 Apr 2021 17:06:45
	(b) (4)	
Signature has been broken.	Lauren Hewitt (b) (4)	08 Apr 2021 17:06:45
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lauren Hewitt (b) (4)	08 Apr 2021 17:06:45
	(b) (4)	
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:46:15
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
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, please keep query open until achieved. Query reminders will be sent periodically for event resolution.' (Site from Safety). 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, please keep query open until achieved. Query reminders will be sent periodically for event resolution.' answered with 'End date provided. Please resolve. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:57:32
DataPoint Un-verified.	Lauren Hewitt (b) (4)	08 Apr 2021 17:07:13
Signature has been broken.	(b) (4)	
	Lauren Hewitt (b) (4)	08 Apr 2021 17:06:45
	(b) (4)	
User entered '13 Jan 2021' reason for change: New Information	Lauren Hewitt (b) (4)	08 Apr 2021 17:06:45
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, please keep query open until achieved. Query reminders will be sent periodically for event resolution.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:34:59
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, please keep query open until achieved. Query reminders will be sent periodically for event resolution.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:35:29
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, please keep query open until achieved. Query reminders will be sent periodically for event resolution.' answered with 'Event is ongoing. (b) (6) 5 April 2021' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 20:29:27

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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, please keep query open until achieved. Query reminders will be sent periodically for event resolution.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Mar 2021 14:04:00
	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
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)	11 Mar 2021 17:10:26
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 'UPDATE 10MAR 2021: PPT STATES SHE STILL HAS INTERMITTENT SOB AND IS UNSURE IF IT IS RELATED TO HER PULMONARY EMBOLISM OR OTHER UNDERLYING LUNG ISSUES. HAS APPT "LATE MARCH, EARLY APRIL -- I AM NOT SURE" FOR RECHECK WITH PULMONOLOGIST FOR RESOLUTION OF P.E. SHOULD WE LEAVE THIS "ONGOING", OR CLOSE THIS SAE/ACUTE PE EPISODE "WITH SEQUELAE", OR HANDLE IN ANOTHER MANNER?' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 17:31:29
Comment added 'PPT LAST SEEN IN JAN 2021 WHEN SHE INDICATED HER LAST SCAN SHOWED ONLY 1 OF HER PRIOR MULTIPLE EMBOLI IS REMAINING.'	(b) (4), (b) (6)	10 Mar 2021 17:26:58
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)	22 Jan 2021 21:00:36
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:46:23
User entered empty.	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:46:24
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) (6)	15 Jan 2021 12:58:29
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 'Subject has follow up scan to check for PE resolution in 5 months' (Site from Safety).	Hollie Macenczak (b) (4)	14 Jan 2021 21:46:54
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)	29 Dec 2020 15:32:35
User entered empty.	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:50:45
User entered 'Grade 4 (Grade 4)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:54
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:56
User entered '0'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:51:57
User entered 'I'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:52:05
User entered 'I'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:55:17
User entered '18 Dec 2020'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:55:19
User entered '21 Dec 2020'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:56:39
User entered 'No (N)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:37
User entered empty.	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:39
User entered '0'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:40
User entered '0'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:42
User entered '0'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:59:45
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4) 	22 Dec 2020 02:14:54

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:47
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:59:49
User entered 'Not Applicable (NOT APPLICABLE)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:50
User entered '0'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:59:52
User entered 'I'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'PV Query: When known, please provide dates and results of subject CT scans.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:11:09
Query 'PV Query: When known, please provide dates and results of subject CT scans.' answered with 'Already provided' (Site from Safety).	Hollie Macenczak (b) (4)	10 Mar 2021 17:59:54
User opened query 'PV Query: When known, please provide dates and results of subject CT scans.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 15:06:08
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:36:43
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated to include chest CT that was performed upon admission on 18-DEC-2021' (Site from DM).	Hollie Macenczak (b) (4)	17 Feb 2021 17:42:56
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:13:47
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 19:59:54
User entered 'I'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
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. Query reminders will be sent periodically for event resolution.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:57:38
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. Query reminders will be sent periodically for event resolution.' answered with 'Event outcome updated. Please resolve.' (Site from Safety).	Lauren Hewitt (b) (4) (b) (4)	08 Apr 2021 17:07:27
DataPoint Un-verified.	Lauren Hewitt (b) (4) (b) (4)	08 Apr 2021 17:06:45
Signature has been broken.	Lauren Hewitt (b) (4) (b) (4)	08 Apr 2021 17:06:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Lauren Hewitt (b) (4) (b) (4)	08 Apr 2021 17:06:45
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. Query reminders will be sent periodically for event resolution.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 14:04:53
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	13 Mar 2021 03:24:42
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) (6)	11 Mar 2021 17:11:02

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[Outcome](#)

Audit	User	Time (GMT)
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 'SPONE WITH PPT TODAY, 10MAR 2021. PPT WITH ONGOING INTERMITTENT SOB WHICH SHE IS UNSURE IF IT IS RELATED TO HER UNDERLYING PRIOR LUNG ISSUES OR THE PE _s . AS OF LAST SCAN IN JANUARY, SHE HAD 1 REMAINING EMBOLUS. HAS FOLLOW UP LATE MAR-EARLY APR 2021 WITH PULMONOLOGIST TO RE-EVAL and DETERMINE STATUS. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 17:39:44
	(b) (4), (b) (6)	21 Jan 2021 19:59:57
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)	29 Dec 2020 15:33:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:14
User entered empty.	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:03:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:56:03
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:56:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records sent to Safety_Moderna@iqvia.com' (Site from Safety).	Hollie Macenczak (b) (4)	15 Jan 2021 14:39:20
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records sent to Safety_Moderna@iqvia.com' (Site from Safety).	Hollie Macenczak (b) (4)	15 Jan 2021 14:39:15
User closed query 'PV Query: Please provide labile oxygen readings.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 12:58:34
Query 'PV Query: Please provide labile oxygen readings.' answered with 'provided' (Site from Safety).	Hollie Macenczak (b) (4)	14 Jan 2021 21:41:34

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT BEGAN EXPERIENCING SOB (ABOVE BASELINE) WITH FATIGUE ON 18DEC2020. STUDY TEAM RECOMMENDED GOING TO ED FOR WORSENING COVID-19 SYMPTOMS. SUBJECT FOUND TO HAVE ACUTE PULMONARY EMBOLI INVOLVING RIGHT UPPER/LOWER LOBES. TRIGGER FOR EMBOLUS UNKNOWN. THOUGHT TO BE RELATED TO DECREASE IN ACTIVITY SINCE BEGINNING OF PANDEMIC. COVID NEGATIVE. LABILE OXYGEN READINGS (83%-94%) REPORTED AT DAY 4 TELEMEDICINE VISIT.' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	14 Jan 2021 21:41:18
User opened query 'PV Query: Please provide labile oxygen readings.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:34:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:34:08
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:33:59
User entered 'SUBJECT BEGAN EXPERIENCING SOB (ABOVE BASELINE) WITH FATIGUE ON 18DEC2020. STUDY TEAM RECOMMENDED GOING TO ED FOR WORSENING COVID-19 SYMPTOMS. SUBJECT FOUND TO HAVE ACUTE PULMONARY EMBOLI INVOLVING RIGHT UPPER/LOWER LOBES. TRIGGER FOR EMBOLUS UNKNOWN. THOUGHT TO BE RELATED TO DECREASE IN ACTIVITY SINCE BEGINNING OF PANDEMIC. COVID NEGATIVE. LABILE OXYGEN READINGS REPORTED AT DAY 4 TELEMEDICINE VISIT.' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	22 Dec 2020 02:19:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT BEGAN EXPERIENCING SOB (ABOVE BASELINE) WITH FATIGUE ON 18DEC2020. STUDY TEAM RECOMMENDED GOING TO ED FOR WORSENING COVID-19 SYMPTOMS. SUBJECT FOUND TO HAVE ACUTE PULMONARY EMBOLI INVOLVING RIGHT UPPER/LOWER LOBES. TRIGGER FOR EMBOLUS UNKNOWN. THOUGHT TO BE RELATED TO DECREASE IN ACTIVITY SINCE BEGINNING OF PANDEMIC. COVID NEGATIVE. LABILE OXYGEN READINGS REPORTED AT DAY 4 TELEMEDICINE VISIT.'	Hollie Macenczak (b) (4)	22 Dec 2020 02:19:08
reason for change: Data Entry Error		
User entered 'Subject began experiencing SOB (above baseline) with fatigue on 18DEC2020. Study team recommended going to ED for worsening COVID-19 symptoms. Subject found to have acute pulmonary emboli involving right upper/lower lobes. Trigger for embolus unknown. Thought to be related to decrease in activity since beginning of pandemic. COVID negative.'	Hollie Macenczak (b) (4)	22 Dec 2020 02:14:54

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	22 Dec 2020 02:14:54

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 02:14:54

US3482267

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 02:14:54

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Nasopharyngitis, LLT: Common cold - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 15:15:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:15:52
Data point term sent to Coder	System	15 Jan 2021 15:14:35
User entered 'common cold'	Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Yes (Y)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '10 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User entered empty.	System	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:14:38
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	15 Jan 2021 15:14:58
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	15 Jan 2021 15:14:58
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	15 Jan 2021 15:14:58
User entered '13 Jan 2021' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Jan 2021 15:14:58
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	15 Jan 2021 15:14:38
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	15 Jan 2021 15:13:56
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User entered empty.	System	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
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.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:35:52
' (Site from DM).		
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.	(b) (4), (b) (6)	16 Feb 2021 15:25:16
' answered with 'Aleve taken for headache 13 DEC 2020.' (Site from DM).		
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.	(b) (4), (b) (6)	08 Feb 2021 07:09:31
' (Site from DM).		
User entered 'I'	Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

US3482267

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'RELATED TO ILLNESS VISIT SYMPTOMS NOTED ON SYMPTOM LOG.'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User entered '0'	System	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58
User entered 'I'	System	15 Jan 2021 15:13:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:58

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:16:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 19:16:43
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	13 Mar 2021 03:24:42
Data point term sent to Coder	System	10 Mar 2021 17:35:25
User entered 'OSTEOARTHROSIS INVOLVING LOWER LEGS (BILATERAL KNEES), WORSENING' reason for change: New Information	(b) (4), (b) (6) (b) (4)	10 Mar 2021 17:34:59
Data point term sent to Coder	System	08 Mar 2021 20:43:18
User entered 'OSTEOARTHROSIS INVOLVING LOWER LEGS Worsening'	(b) (4), (b) (6) (b) (4)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	17 Mar 2021 14:38:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:38:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 20:42:18

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:30:23
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE is ongoing. (b) (6) 06 April 2021.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:40:06
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:23:34
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
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	10 Mar 2021 17:34:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Per Query Resolution	System	10 Mar 2021 17:34:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 17:34:59
User entered empty.	System	08 Mar 2021 20:42:18
	(b) (4), (b) (6)	08 Mar 2021 20:42:18

US3482267

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

US3482267

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

US3482267

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

US3482267

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

US3482267

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

US3482267

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

None

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	17 Mar 2021 14:39:25
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 14:39:25
	(b) (4), (b) (6)	
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:39:25
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	17 Mar 2021 14:38:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Mar 2021 20:43:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:43:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	08 Mar 2021 20:42:18
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of OSTEOARTHROSIS. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 11:00:34
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of OSTEOARTHROSIS. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' answered with 'Subject was given 2 cortisone injections (one in each knee) on 31 Mar 2021. Cortisone has been added to conmeds. (b) (6) (b) (6) 06 April 2021' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:41:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of OSTEOARTHROSIS. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:02:32
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 14:38:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 14:38:49
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'SUBJECT REPORTS THAT ARTHRITIS IN HER KNEES HAS WORSENERD SINCE 15 DEC 2020. SHE HAS BEEN TRYING TO GET AN ORTHOPEDIST APPOINTMENT. UPDATE 10MAR 2021: PPT HAS APPT WITH ORTHO 31MAR 2021 FOR EVAL AND TO DISCUSS INTERVENTIONS THAT MAY BE TX OPTIONS. USED TYLENOL AND DICLOFENAC GEL. Subject was given a cortisone injection in each knee on 31 Mar 2021.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:42:06
Signature has been broken.	(b) (4), (b) (6)	17 Mar 2021 14:40:01
User entered 'SUBJECT REPORTS THAT ARTHRITIS IN HER KNEES HAS WORSENERD SINCE 15 DEC 2020. SHE HAS BEEN TRYING TO GET AN ORTHOPEDIST APPOINTMENT. UPDATE 10MAR 2021: PPT HAS APPT WITH ORTHO 31MAR 2021 FOR EVAL AND TO DISCUSS INTERVENTIONS THAT MAY BE TX OPTIONS. Used Tylenol and diclofenac gel.' reason for change: New Information	(b) (4), (b) (6)	17 Mar 2021 14:40:01
User signature succeeded.	Nadine Rouphael (b) (4)	13 Mar 2021 03:24:42
User entered 'SUBJECT REPORTS THAT ARTHRITIS IN HER KNEES HAS WORSENERD SINCE 15 DEC 2020. SHE HAS BEEN TRYING TO GET AN ORTHOPEDIST APPOINTMENT. UPDATE 10MAR 2021: PPT HAS APPT WITH ORTHO 31MAR 2021 FOR EVAL AND TO DISCUSS INTERVENTIONS THAT MAY BE TX OPTIONS' reason for change: New Information	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:34:59
User entered 'Subject reports that arthritis in her knees has worsened since 15 Dec 2020. She has been trying to get an orthopedist appointment.'	(b) (4), (b) (6)	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 20:42:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:49:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:38:49
User entered '0'	System	08 Mar 2021 20:42:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:49:35

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:17:42
User closed query 'Per ETRTR: Other action taken for SAE "ACUTE PULMONARY EMBOLI" is Concomitant Medication however medication for this event is not present for this event. Please update.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 20:17:39
Query 'Per ETRTR: Other action taken for SAE "ACUTE PULMONARY EMBOLI" is Concomitant Medication however medication for this event is not present for this event. Please update.' answered with 'updated' (Site from CRA).	Hollie Macenczak (b) (4)	15 Jan 2021 15:03:23
User opened query 'Per ETRTR: Other action taken for SAE "ACUTE PULMONARY EMBOLI" is Concomitant Medication however medication for this event is not present for this event. Please update.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 17:44:39
User entered 'Yes (Y)'	Easton Beshears (b) (4) (b) (4)	11 Sep 2020 14:22:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 10:45:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 10:45:29
Data point term sent to Coder	System	02 Nov 2020 15:21:23
Coding entries removed.	(b) (4), (b) (6)	02 Nov 2020 15:21:04
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: LATANOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:34:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:34:42
Data point term sent to Coder	System	14 Sep 2020 12:34:07
User entered 'latanoprost'	Easton Beshears (b) (4)	14 Sep 2020 12:33:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'glaucoma'	(b) (4) Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '1'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Other (OTHER)'	Easton Beshears (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'drop each eye'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
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)	25 Nov 2020 07:00:54
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 to ophthalmic' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:21:12
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 15:21:04
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)	28 Oct 2020 01:57:53
User entered 'Intraocular (INTRAOCULAR)'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'ophthalmic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:21:04
User entered empty.	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2015'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:35:16
User entered 'No (N)' reason for change: Data Entry Error	System	14 Sep 2020 17:35:16
User opened query 'Data is required. Please complete.' (Site from System).	Easton Beshears (b) (4)	14 Sep 2020 17:35:16
User entered empty.	(b) (4)	
	System	14 Sep 2020 12:33:55
	Easton Beshears (b) (4)	14 Sep 2020 12:33:55
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:33:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: CARBONIC ANHYDRASE INHIBITORS, PRODUCT: BRINZOLAMIDE, PRODUCTSYNONYM: AZOPT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 10:52:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 10:52:14
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	02 Nov 2020 15:22:24 02 Nov 2020 15:21:35
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: CARBONIC ANHYDRASE INHIBITORS, PRODUCT: BRINZOLAMIDE, PRODUCTSYNONYM: AZOPT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:36:47
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 Sep 2020 12:36:47
Data point term sent to Coder User entered 'azopt'	System Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:36:09 14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'glaucoma'	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '1'	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Other (OTHER)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'drop each eye'	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
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)	25 Nov 2020 07:01:20
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 to ophthalmic' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:21:43
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 15:21:35
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)	28 Oct 2020 01:58:23
User entered 'Intraocular (INTRAOCULAR)'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'ophthalmic' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:21:35
User entered empty.	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2015'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:36:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Sep 2020 14:19:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:19:43
Data point term sent to Coder	System	14 Sep 2020 12:37:09
User entered 'simvastatin'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'heart health'	(b) (4) Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '40'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2001'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:36:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 12:38:42
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 Sep 2020 12:38:42
Data point term sent to Coder	System	14 Sep 2020 12:38:10
User entered 'escitalopram'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'depression'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '30'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2018'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:37:35

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:39:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:39:48
Data point term sent to Coder	System	14 Sep 2020 12:39:10
User entered 'aspirin'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'coronary artery disease prevention'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '81'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'UN UNK 2010' reason for change:	(b) (4)	
Data Entry Error	Easton Beshears (b) (4)	15 Sep 2020 17:46:00
User entered 'un UNK 2001'	(b) (4)	
	Easton Beshears (b) (4)	14 Sep 2020 12:38:50
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:38:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:41:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:41:51
Data point term sent to Coder	System	14 Sep 2020 12:40:13
User entered 'clonazepam'	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'anxiety'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0.5'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	Easton Beshears (b) (4)	15 Sep 2020 17:46:34
User entered 'once daily (QD)'	(b) (4)	
	Easton Beshears (b) (4)	14 Sep 2020 12:40:09
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2006'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:46:34
User entered '1'	System	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:46:34
User entered '1'	System	14 Sep 2020 12:40:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 17:46:34
User entered '804 (804)'	System	14 Sep 2020 12:40:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 16:40:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:40:21
Data point term sent to Coder	System	05 Nov 2020 16:39:25
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:39:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:42:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:42:55
Data point term sent to Coder	System	14 Sep 2020 12:41:13
User entered 'flonase'	Easton Beshears (b) (4)	14 Sep 2020 12:40:57
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med # 07 and # 15 use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 11:39:11
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med # 07 and # 15 use, add a medical condition and all applicable details to the appropriate MH eCRF.' answered with '"seasonal allergies" added to medical history' (Site from DM).	Hollie Macenczak (b) (4)	15 Jan 2021 14:56:27
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med # 07 and # 15 use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:35:08
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:37:49
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:39:12
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:39:07
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:58:54
User entered 'allergies'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
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 for ongoing medication, if known.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 07:03:22
Query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose for ongoing medication, if known.' answered with 'updated unknown to unk' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:04:04
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:03:43
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 for ongoing medication, if known.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:38:03
User closed query 'Per DM CLR: Please review medication and include the actuation of this medication in the Medication Name field (eg. Flonase 27.5 mcg, 50 mcg, 93 mcg, etc) as the number of puff/sprays is already recorded in the Dose and Dose Unit fields.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:38:03
Query 'Per DM CLR: Please review medication and include the actuation of this medication in the Medication Name field (eg. Flonase 27.5 mcg, 50 mcg, 93 mcg, etc) as the number of puff/sprays is already recorded in the Dose and Dose Unit fields.' answered with 'updated to unknown as patient was not certain on dose per administration' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 17:43:13
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 17:42:40
User opened query 'Per DM CLR: Please review medication and include the actuation of this medication in the Medication Name field (eg. Flonase 27.5 mcg, 50 mcg, 93 mcg, etc) as the number of puff/sprays is already recorded in the Dose and Dose Unit fields.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:59:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'puff (PUFF)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Nasal (NASAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2015'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:40:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 12:42:55
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 Sep 2020 12:42:55
Data point term sent to Coder	System	14 Sep 2020 12:42:14
User entered 'pramiprexole'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Restless leg syndrome'	(b) (4) Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0.25'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2010'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:41:55

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
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)	14 Sep 2020 12:44:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:44:40
Data point term sent to Coder	System	14 Sep 2020 12:44:15
User entered 'albuterol'	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'asthma'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '2'	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'puff (PUFF)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2016'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 12:43:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:46:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 12:46:53
Data point term sent to Coder	System	14 Sep 2020 12:45:16
User entered 'symbicort 160/4.5 mcg'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'asthma'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '1'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'puff (PUFF)'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'twice daily (BID)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2016'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 12:44:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Sep 2020 12:46:53
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 Sep 2020 12:46:53
Data point term sent to Coder	System	14 Sep 2020 12:45:15
User entered 'lisinopril'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'hypertension'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '10'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2018'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)' reason for change: New Information	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:31:34
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '20 Dec 2020' reason for change: New Information	(b) (4)	
	Michelle Wiles (b) (4)	14 Jan 2021 16:31:34
User entered empty.	(b) (4)	
	Easton Beshears (b) (4)	14 Sep 2020 12:45:09
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User entered '1'	System	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User entered '1'	System	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:34
User entered '804 (804)'	System	14 Sep 2020 12:45:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: FOSAMAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Sep 2020 12:46:53
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 Sep 2020 12:46:53
Data point term sent to Coder	System	14 Sep 2020 12:46:17
User entered 'fosamax'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'osteoporosis'	(b) (4) Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '70'	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'every week (QS)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2015'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	14 Sep 2020 12:46:09

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 16:08:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:08:54
Data point term sent to Coder Coding entries removed.	System Hollie Macenczak (b) (4)	15 Jan 2021 15:45:05 15 Jan 2021 15:44:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 09:04:32
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 Nov 2020 09:04:32
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Nov 2020 16:40:26 05 Nov 2020 16:39:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:52:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'diclofenac 1% gel'	Coder Import (b) (4) (b) (4) System Easton Beshears (b) (4) (b) (4)	14 Sep 2020 15:52:48 14 Sep 2020 12:47:18 14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:13:08
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated medical history' (Site from DM).	Hollie Macenczak (b) (4)	15 Jan 2021 15:44:58
User entered 'bilateral KNEE PAIN associated with osteoarthritis' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	15 Jan 2021 15:44:50
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use, add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:36:02
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:00:11
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'updated to knee pain' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:40:06
User entered 'knee PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:39:55
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 02:00:03
User entered 'pain'	Easton Beshears (b) (4) (b) (4)	14 Sep 2020 12:47:06

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EAB) (1725)

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US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '1'	Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Other (OTHER)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'application'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Topical (TOPICAL)'	Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'un UNK 2015'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 12:47:06

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per CDM re-query: Site response noted; Moderate asthma is present in MH. However 'Seasonal Allergies' is not recorded in MH / AE eCRF. Please review and add this medical condition in MH / AE eCRF as appropriate else clarify in query response. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 12:39:29
Query 'Per CDM re-query: Site response noted; Moderate asthma is present in MH. However 'Seasonal Allergies' is not recorded in MH / AE eCRF. Please review and add this medical condition in MH / AE eCRF as appropriate else clarify in query response. Thank you' answered with 'seasonal allergies added to medical history' (Site from DM).	Hollie Macenczak (b) (4)	15 Jan 2021 14:58:21
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:23:35
User opened query 'Per CDM re-query: Site response noted; Moderate asthma is present in MH. However 'Seasonal Allergies' is not recorded in MH / AE eCRF. Please review and add this medical condition in MH / AE eCRF as appropriate else clarify in query response. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:23:33
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'moderate asthma as well as seasonal allergies ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 18:13:55
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:45:23

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4)	02 Oct 2020 19:46:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 19:46:43
Data point term sent to Coder	System	02 Oct 2020 19:45:08
User entered 'Loratidine'	Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'seasonal allergies'	(b) (4) Easton Beshears (b) (4) (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '10'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '1 Oct 2020'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Easton Beshears (b) (4)	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:45:01

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Oct 2020 18:57:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 18:57:55
Data point term sent to Coder	System	30 Oct 2020 18:57:17
User entered 'zytrec'	(b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'seasonal allergies'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'unk'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 18:57:02

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
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)	15 Jan 2021 15:00:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 15:00:52
Data point term sent to Coder	System	15 Jan 2021 15:00:29
Coding entries removed.	Hollie Macenczak (b) (4)	15 Jan 2021 15:00:22
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)	05 Nov 2020 16:40:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:40:22
Data point term sent to Coder	System	05 Nov 2020 16:39:26
User entered 'flu vaccine'	(b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for FLU). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 01:03:50
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for FLU). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Hollie Macenczak (b) (4)	15 Jan 2021 15:00:31
User entered 'influenza prevention' reason for change: Per Query Resolution	Hollie Macenczak (b) (4)	15 Jan 2021 15:00:22
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for FLU). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:36:37
User entered 'flu season'	(b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'dose'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User entered empty.	System	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User entered empty.	System	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:29:21
User entered empty.	System	05 Nov 2020 16:38:47

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:26:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:26:42
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:19:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:19:48
Data point term sent to Coder	System	15 Dec 2020 19:15:08
Coding entries removed.	Hollie Macenczak (b) (4)	15 Dec 2020 19:14:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 15:58:50

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Benadryl'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	15 Dec 2020 15:58:50 14 Dec 2020 20:02:39 14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'ITCHING IN HANDS related to rash (AE #4)' reason for change: New Information	Hollie Macenczak (b) (4)	15 Dec 2020 19:14:56
User entered 'Itching in hands'	(b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '25'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:51:20
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:51:20
User entered '12 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 07:37:05
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'The medication was taken for AE 4, not a solicited event. (b) (6) 8 Mar 2021' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 20:07:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:06:58
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:41:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 20:02:28

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:24:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:24:52
Data point term sent to Coder Coding entries removed.	System Lauren Hewitt (b) (4) (b) (4)	08 Apr 2021 15:24:01 08 Apr 2021 15:23:36
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:32:37
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 17:20:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 17:20:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	16 Feb 2021 15:25:21 16 Feb 2021 15:24:26

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:06:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:06:52
Data point term sent to Coder	System	15 Jan 2021 15:04:31
Data point term sent to Coder	System	15 Jan 2021 15:03:30
Coding entries removed.	Hollie Macenczak (b) (4) (b) (4) (b) (4)	15 Jan 2021 15:02:56
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:06:01
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 Dec 2020 20:06:01
Data point term sent to Coder	System	14 Dec 2020 20:04:43
User entered 'aleve'	(b) (4), (b) (6) (b) (4)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
Signature has been broken.	(b) (4)	
	Lauren Hewitt (b) (4)	08 Apr 2021 15:23:36
	(b) (4)	
User entered 'HEADACHE ASSOCIATED WITH AE #6' reason for change: Data Entry Error	Lauren Hewitt (b) (4)	08 Apr 2021 15:23:36
User signature succeeded.	(b) (4)	
	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'HEADACHE ASSOCIATED WITH AE #7' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:24:26
User entered 'HEADACHE ASSOCIATED WITH AE #6' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Jan 2021 15:03:54
User entered 'HEADACHE associated with AE #5' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Jan 2021 15:02:56
User entered 'headache'	(b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 07:37:31
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Data entry error, one Aleve tablet is 220 mg rather than 110 mg. (b) (6) 8 Mar 2021' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 20:22:43
User entered '220' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 20:17:11
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:42:39
User entered '110'	(b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User closed query 'Per DM CLR/Requery: Response noted. However, please note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:42:33
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
Query 'Per DM CLR/Requery: Response noted. However, please note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' answered with 'This medication was not taken for a solicited event but rather an AE. Indication was updated to reflect appropriate AE. Please resolve. ' (Site from DM). Signature has been broken.	(b) (4) Lauren Hewitt (b) (4)	08 Apr 2021 15:25:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Lauren Hewitt (b) (4)	08 Apr 2021 15:23:36
User opened query 'Per DM CLR/Requery: Response noted. However, please note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 04:15:16
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 04:12:08
Data hard locked.	(b) (4), (b) (6)	08 Apr 2021 04:12:03
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes. However, this condition is not recorded in Diary and after AE reporting of 7 days after each IP. Review if this field should be checked as NO and condition of Headache should be recorded in AE ecrf. Review and update as appropriate Else, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:31:58
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes. However, this condition is not recorded in Diary and after AE reporting of 7 days after each IP. Review if this field should be checked as NO and condition of Headache should be recorded in AE ecrf. Review and update as appropriate Else, clarify.' answered with 'Subject reported symptoms in diary on 12 Dec 20 that prompted a call on 14 Dec 20. During the phone call, the subject reported that she had been experiencing headache, sore throat, and runny nose, prompting an illness visit. (b) (6) 8 Mar 2021' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 20:25:41
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes. However, this condition is not recorded in Diary and after AE reporting of 7 days after each IP. Review if this field should be checked as NO and condition of Headache should be recorded in AE ecrf. Review and update as appropriate Else, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:51:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User entered empty.	System	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User entered empty.	System	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:23
User entered empty.	System	14 Dec 2020 20:03:49

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: TERBINAFINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 23:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 23:34:42
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Mar 2021 17:32:47 04 Mar 2021 17:32:06
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: TERBINAFINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:05:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 23:05:42
Data point term sent to Coder User entered 'terbinafine hydrochloride 1%'	System Hollie Macenczak (b) (4)	15 Dec 2020 19:22:19 15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of RASH (Urticarial vs. Non-urticarial). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:35:57
Query 'Per DM CLR: Please update the indication to reflect the location and type of RASH (Urticarial vs. Non-urticarial). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'SEE AE #4.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:32:23
User entered 'RASH ON BILATERAL HANDS (AE #4)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Mar 2021 17:32:06
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of RASH (Urticarial vs. Non-urticarial). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:46:17
User entered 'rash on bilateral hands'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered '1'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'Other (OTHER)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'application'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'as needed (PRN)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Topical (TOPICAL)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'I'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered empty.	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 19:21:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 16:39:56
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 Jan 2021 16:39:56
Data point term sent to Coder	System	14 Jan 2021 16:38:46
User entered 'Eliquis'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:16
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:18
User entered 'Acute Pulmonary Embolism'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:19
User entered '10'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:21
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:23
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:29
User entered 'twice daily (BID)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:30
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:33
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:35
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:37
User entered '20 Dec 2020' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Jan 2021 15:29:46
User entered '21 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:38
User entered '0'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:21:40
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:27:44
User entered '26 Dec 2020'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:27:46
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User entered '2'	System	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User entered '1'	System	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 04:20:13
User entered '804 (804)'	System	14 Jan 2021 16:38:10

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:27:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Jan 2021 16:39:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Jan 2021 16:39:56
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 16:38:46
User entered 'Eliquis'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:27:56
User entered 'No (N)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:27:58
User entered 'Acute Pulmonary Embolism'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:27:59
User entered '5'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:28:01
User entered 'mg (mg)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:02
User entered empty.	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:03
User entered 'twice daily (BID)'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:28:05
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:28:07
User entered 'Oral (ORAL)'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:28:09
User entered empty.	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:10
User entered '27 Dec 2020'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:12
User entered '0'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:14
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:15
User entered empty.	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:28:17
User entered 'No (N)'	Michelle Wiles (b) (4)	14 Jan 2021 16:38:42
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Jan 2021 16:38:42

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:01
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:25:53
Data point term sent to Coder	System	15 Jan 2021 15:24:56
Coding entries removed.	Hollie Macenczak (b) (4)	15 Jan 2021 15:24:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:31:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:31:02
Data point term sent to Coder	System	14 Jan 2021 16:39:47
User entered 'Lisinopril'	Michelle Wiles (b) (4) (b) (4)	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:02
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:39
User entered 'No (N)'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:04
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:41
User entered 'HYYPERTENSION' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	15 Jan 2021 15:24:24
User entered 'HyHypertension'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:05
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:42
User entered '20'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:07
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:43
User entered 'mg (mg)'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:08
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:58
User entered empty.	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'once daily (QD)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:36:27
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'Dosage was increased due to AE pulmonary emboli not a worsening of an existing condition.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:06:19
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:39:26
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 20:29:10
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:54
User entered '21 Dec 2020'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:12
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:52
User entered '0'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:13
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:51
User entered 'Yes (Y)'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:15
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:49
User entered empty.	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:29:16
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:28:48
User entered 'No (N)'	Michelle Wiles (b) (4)	14 Jan 2021 16:39:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Jan 2021 16:39:18

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
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, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:25:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:25:52
Data point term sent to Coder	System	07 Apr 2021 14:12:37
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 14:11:51
User signature succeeded.	Nadine Rouphael (b) (4) (b) (4)	26 Mar 2021 22:32:37
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, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:18:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:18:53
Data point term sent to Coder	System	15 Jan 2021 15:17:48
User entered 'ADVIL'	Hollie Macenczak (b) (4) (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:36:33
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated indication' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:12:04
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 14:11:51
User entered 'Common Cold' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:11:51
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:37:08
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'HEADACHE'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '400'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '13 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '13 Dec 2020' reason for change: Data Entry Error	System	15 Jan 2021 15:17:07
	Hollie Macenczak (b) (4)	15 Jan 2021 15:17:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 15:16:57
User entered '13 Dec 202' (non-conformant).	Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) Hollie Macenczak (b) (4)	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User entered empty.	System	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User entered empty.	System	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 08:06:35
User entered empty.	System	15 Jan 2021 15:16:57

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:39:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 15:39:54
Data point term sent to Coder	System	15 Jan 2021 15:37:01
User entered 'heparin high dose bolus'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:33
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:34
User entered 'pulmonary emboli'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:36
User entered '6800'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per CDM: IU is one of available options for Dose unit. Please consider changing dose unit from 'Other' to IU and remove value from 'If dose unit is Other, specify' field, otherwise explain. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 23:36:55
Query 'Per CDM: IU is one of available options for Dose unit. Please consider changing dose unit from 'Other' to IU and remove value from 'If dose unit is Other, specify' field, otherwise explain. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:35:11
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:35:00
User entered 'IU (IU)' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Mar 2021 17:35:00
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:29:38
User opened query 'Per CDM: IU is one of available options for Dose unit. Please consider changing dose unit from 'Other' to IU and remove value from 'If dose unit is Other, specify' field, otherwise explain. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 11:04:37
User entered 'Other (OTHER)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:35:00
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	04 Mar 2021 17:35:00
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:29:46
User entered 'units'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:48
User entered 'once (ONCE)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:49
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:51
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:29:53
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:30:37
User entered '18 Dec 2020'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:13
User entered '0'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:15
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:17
User entered '18 Dec 2020'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:19
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User entered empty.	System	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User entered empty.	System	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:42:11
User entered empty.	System	15 Jan 2021 15:36:37

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:07:54
Data point term sent to Coder	System	15 Jan 2021 15:40:03
User entered 'heparin'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:37
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:38
User entered 'pulmonary emboli'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:31:40
User entered '15-18'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:00
User entered 'Other (OTHER)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:02
User entered 'unit/kg/hr'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:10
User entered 'other (OTHER)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:13
User entered 'continuous titrated infusion'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:15
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:16
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:35
User entered '18 Dec 2020'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:33:44
User entered '0'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:33:45
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:33:51
User entered '20 Dec 2020'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:33:53
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User entered empty.	System	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User entered empty.	System	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:37:29
User entered empty.	System	15 Jan 2021 15:39:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User closed query 'Per source, patient had 2 puffs of Symbicort on 18Dec2020. Please confirm and add.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:14:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:41:41
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 Apr 2021 09:41:41
Data point term sent to Coder	System	07 Apr 2021 14:22:46
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 14:22:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Per source, patient received 650mg Tylenol while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:37:19
Query 'Per source, patient received 650mg Tylenol while hospitalized. Please confirm and update.' answered with 'ACETAMINOPHEN UPDATED.' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 13:23:34
Query 'Per source, patient had 2 puffs of Symbicort on 18Dec2020. Please confirm and add.' answered with 'SYMBICORT WAS ALREADY HER BASELINE MED; SEE CON MEDS LIST.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:34:17
User opened query 'Per source, patient received 650mg Tylenol while hospitalized. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 21:39:49
User opened query 'Per source, patient had 2 puffs of Symbicort on 18Dec2020. Please confirm and add.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 21:37:04
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:32:12

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:10:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:10:53
Data point term sent to Coder	System	15 Jan 2021 15:44:04
User entered 'potassium chloride'	Hollie Macenczak (b) (4) (b) (4) (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:13
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
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)	08 Apr 2021 13:36:44
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 'reconciled' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:22:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 14:22:36
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 14:22:36
User entered 'Supplementation (ASSOCIATED WITH AE #5)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:22:36
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)	07 Apr 2021 05:41:42
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:15
User entered 'standard of care for diagnosis while hospitalized (associated with AE #5)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:17
User entered '20'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:19
User entered 'Other (OTHER)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:24
User entered 'mEq'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:28
User entered 'once (ONCE)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:29
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:31
User entered 'Oral (ORAL)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:32
User entered empty.	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:34
User entered '21 Dec 2020'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:35
User entered '0'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:43
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:45
User entered '21 Dec 2020'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:32:46
User entered 'No (N)'	Hollie Macenczak (b) (4)	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User entered empty.	System	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User entered empty.	System	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:16
User entered empty.	System	15 Jan 2021 15:43:19

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUOCINONIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 13:46:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:46:56
Data point term sent to Coder	System	08 Mar 2021 20:48:24
User entered 'Fluocinonide 0.05%'	(b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'AE #4 Rash'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0.05'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Percent'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User entered '3'	System	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User entered '1'	System	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 05:33:36
User entered '804 (804)'	System	08 Mar 2021 20:47:29

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 13:11:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 13:11:44
Data point term sent to Coder	System	12 Mar 2021 13:10:53
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'PAIN DURING HOSPITAL ADMISSION (AE #5)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '650'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User entered empty.	System	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User entered empty.	System	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 07:33:54
User entered empty.	System	12 Mar 2021 13:10:27

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 13:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 13:18:44
Data point term sent to Coder	System	12 Mar 2021 13:17:55
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'KNEE PAIN'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '500'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
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	12 Mar 2021 13:17:25
User entered 'Oral (ORAL)' reason for change: Data Entry Error	System	12 Mar 2021 13:17:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 13:17:25
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:17:16

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 08:29:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:29:58
Data point term sent to Coder	System	06 Apr 2021 14:39:25
User entered 'Cortisone'	(b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'AE 8 Worsening Osteoarthritis'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	08 Apr 2021 16:22:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:49:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 14:39:14

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:49:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:54:07
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Yes (Y)'	(b) (4) Easton Beshears (b) (4)	06 Oct 2020 15:02:51

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:49:35

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '23 Sep 2020' reason for change: Data Entry Error	System	15 Oct 2020 18:33:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 18:33:43
User entered 'UN Sep 2020' (non-conformant).	System	06 Oct 2020 15:04:38
	Easton Beshears (b) (4)	06 Oct 2020 15:04:38
	(b) (4)	

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:49:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Cardiac Stress Test'	(b) (4) Easton Beshears (b) (4)	06 Oct 2020 15:04:38

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Medical History (MH)'	(b) (4) Easton Beshears (b) (4)	06 Oct 2020 15:04:38

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:49:35

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Easton Beshears (b) (4)	06 Oct 2020 15:04:38

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:49:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered '18 Dec 2020'	(b) (4) Hollie Macenczak (b) (4)	17 Feb 2021 17:42:28

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:49:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'chest CT'	(b) (4) Hollie Macenczak (b) (4)	17 Feb 2021 17:42:28

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:49:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered 'Adverse Event (AE)'	(b) (4) Hollie Macenczak (b) (4)	17 Feb 2021 17:42:28

US3482267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:49:35

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:15
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
User entered empty.	(b) (4) Hollie Macenczak (b) (4)	17 Feb 2021 17:42:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered	System	22 Dec 2020 18:25:06
'USA-US106-2020-MRNA-1273-P301000010'		

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Nadine'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:15:12
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Easton'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Rouphael'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Beshears'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '500 Irvin Court'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'Decatur'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'GA'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '30030'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'US'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 21:58:28
User entered '3'	System	19 Jan 2021 13:56:25
User entered '2'	System	15 Jan 2021 12:59:19
User entered '1'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered	System	22 Dec 2020 18:25:06
'USA-US106-2020-MRNA-1273-P301000010'		

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Nadine'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:15:12
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Easton'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Rouphael'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Beshears'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '500 Irvin Court'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'Decatur'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'GA'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '30030'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'US'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 21:58:28
User entered '3'	System	19 Jan 2021 13:56:25
User entered '2'	System	15 Jan 2021 12:59:19
User entered '1'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:49:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:17:01
User entered '22/Dec/2020 13:25'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:49:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:17:01
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered	System	22 Dec 2020 18:25:06
'USA-US106-2020-MRNA-1273-P301000010'		

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Nadine'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:15:12
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Easton'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Rouphael'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Beshears'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '500 Irvin Court'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'Decatur'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'GA'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '30030'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'US'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 21:58:28
User entered '3'	System	19 Jan 2021 13:56:25
User entered '2'	System	15 Jan 2021 12:59:19
User entered '1'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:49:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:17:01
User entered '15/Jan/2021 12:59'	System	15 Jan 2021 12:59:19

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:49:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:17:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 13:56:16
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 12:59:19

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered	System	22 Dec 2020 18:25:06
'USA-US106-2020-MRNA-1273-P301000010'		

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Nadine'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:15:12
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
	(b) (4), (b) (6)	
User entered 'Easton'	System	22 Dec 2020 18:25:06

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Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Rouphael'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Beshears'	System	22 Dec 2020 18:25:06

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Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '500 Irvin Court'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'Decatur'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'GA'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '30030'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'US'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 21:58:28
User entered '3'	System	19 Jan 2021 13:56:25
User entered '2'	System	15 Jan 2021 12:59:19
User entered '1'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:49:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:17:01
User entered '19/Jan/2021 13:56'	System	19 Jan 2021 13:56:25

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:49:35

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)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 21:57:55
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:17:01
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 13:56:25

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:37
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered	System	22 Dec 2020 18:25:06
'USA-US106-2020-MRNA-1273-P301000010'		

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:39
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Death

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:04
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Yes (Y)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:08
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:15:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'No (N)'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Nadine'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:15:12
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
	(b) (4), (b) (6)	
User entered 'Easton'	System	22 Dec 2020 18:25:06

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
	(b) (4)	
Un-reviewed for Safety.	System	08 Apr 2021 21:58:28
DataPoint Un-verified.	System	08 Apr 2021 21:58:28
Signature has been broken.	System	08 Apr 2021 21:58:28
User entered 'Rouphael'	System	08 Apr 2021 21:58:28
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:16:50
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:25:49
User entered 'Beshears'	System	22 Dec 2020 18:25:06

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Folder: SAE USA-US106-2020-MRNA-1273-P301000010

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Generated On: 09 Jun 2021 17:49:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '500 Irvin Court'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'Decatur'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'GA'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '30030'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	26 Mar 2021 22:32:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 20:16:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:12
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 12:59:08
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:26:09
User entered 'US'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:49:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Apr 2021 21:58:28
User entered '3'	System	19 Jan 2021 13:56:25
User entered '2'	System	15 Jan 2021 12:59:19
User entered '1'	System	22 Dec 2020 18:25:57

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:49:35

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered '08/Apr/2021 17:58'	(b) (4) System	08 Apr 2021 21:58:28

US3482267

Folder: SAE USA-US106-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nadine Rouphael (b) (4)	12 Apr 2021 16:19:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:58:28