

US3232162 (Prod: MediSync Clinical Research Hattiesburg Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:09:18

All time stamps listed in this document are displayed in GMT

US3232162

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

[Participant ID](#)

US3232162

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

US3232162

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	MYOPIA (EYEGLASSES)
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 (2)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	CATARACTS BILATERAL EYES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	DIVERTICULOSIS
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)	

US3232162

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	TYPE 2 DIABETES
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)	

US3232162

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	BASAL CELL SKIN CANCER
Start date (dd MMM yyyy)	10 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	10 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 OCT 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	04 NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 19:03:08

Generated On: 09 Jun 2021 16:09:18

Condition	CHRONIC DIASTOLIC AND SYSTOLIC CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	21 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3232162

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:58
Height (<i>xxx.x</i>)	180 cm
Weight (<i>xxx.x</i>)	126 kg
BMI (<i>xxx.x</i>)	38.88889 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) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 16:11:45

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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) 18 Feb 2021 16:11:45

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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)	False
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 190519

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) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

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) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

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)	11 SEP 2020
Time of assessment (00:00-23:59)	09:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:58
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	173 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

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)	11 SEP 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:20
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	172 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 10:40

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) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	09:58 (24 HR)
Collection date and time (derived)	11 SEP 2020 09:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:59	11 SEP 2020 09:59
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 11:00

PC Close Date & Time

11 SEP 2020 13:30

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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	11 SEP 2020 19:16
PC Open Date & Time	11 SEP 2020 14:25
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 17:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

13 SEP 2020 18:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 16:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

15 SEP 2020 17:00

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 17:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

17 SEP 2020 12:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 11:00

PC Close Date & Time

11 SEP 2020 13:30

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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 19:16

PC Open Date & Time

11 SEP 2020 14:25

PC Close Date & Time

12 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

12 SEP 2020 17:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

13 SEP 2020 18:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

14 SEP 2020 16:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

15 SEP 2020 17:00

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

16 SEP 2020 17:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

17 SEP 2020 12:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 11:00

PC Close Date & Time

11 SEP 2020 13:30

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 19:17
PC Open Date & Time	11 SEP 2020 14:25
PC Close Date & Time	12 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 17:17
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

52 of 2164

EAB) (1725)

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:28
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

54 of 2164

EAB) (1725)

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:04
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 17:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 17:44
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

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EAB) (1725)

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:59
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3232162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

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)	9 OCT 2020
Time of assessment (00:00-23:59)	09:04 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 09:04
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	178 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

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)	9 OCT 2020
Time of assessment (00:00-23:59)	10:24 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 10:24
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3232162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

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) 9 OCT 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 10:08

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

US3232162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	09:15 (24 HR)
Collection date and time (derived)	9 OCT 2020 09:15

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:10	9 OCT 2020 09:10
Nasopharyngeal Swab 2	No		

US3232162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

09 OCT 2020 10:29

PC Open Date & Time

09 OCT 2020 10:28

PC Close Date & Time

09 OCT 2020 12:58

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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 97.8 °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	09 OCT 2020 18:12
PC Open Date & Time	09 OCT 2020 13:53
PC Close Date & Time	10 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 16:39

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

97.6 °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 OCT 2020 21:19

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 18:27

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

97.0 °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 OCT 2020 17:34

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

97.7 °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 17:38

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

15 OCT 2020 17:39

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

09 OCT 2020 10:29

PC Open Date & Time

09 OCT 2020 10:28

PC Close Date & Time

09 OCT 2020 12:58

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

09 OCT 2020 18:13

PC Open Date & Time

09 OCT 2020 13:53

PC Close Date & Time

10 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

10 OCT 2020 16:39

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

11 OCT 2020 21:20

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

12 OCT 2020 18:27

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

13 OCT 2020 17:34

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

14 OCT 2020 17:38

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

15 OCT 2020 17:39

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 10:30
PC Open Date & Time	09 OCT 2020 10:28
PC Close Date & Time	09 OCT 2020 12:58

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 18:14
PC Open Date & Time	09 OCT 2020 13:53
PC Close Date & Time	10 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 16:40
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 21:20
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

100 of 2164

EAB) (1725)

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

		Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 18:28	
PC Open Date & Time	12 OCT 2020 12:00	
PC Close Date & Time	13 OCT 2020 11:59	

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

102 of 2164

EAB) (1725)

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 17:35
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 17:39
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

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 ☒

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 17:39
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3232162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:45

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	8:55 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 8:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3232162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 NOV 2020
Collection time (00:00-23:59)	9:02 (24 HR)
Collection date and time (derived)	6 NOV 2020 9:02

US3232162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:12:12

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 07:00:53

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 <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"/>

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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	22 NOV 2020 11:26:45
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 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	29 NOV 2020 11:12:37
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

10 DEC 2020 17:20:50

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 13:16:29
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 09:46:46

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 07:20:15

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

04 JAN 2021 17:49:07

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 06:13:19
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

19 JAN 2021 09:32:27

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:49:16

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 FEB 2021 06:07:55
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 07:19:40

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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	15 FEB 2021 06:51:57
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 10:02:49
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

28 FEB 2021 07:19:30

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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	07 MAR 2021 13:57:41
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 07:08:12

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 18:01:45

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 06:58:50

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 08:36:07

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

12 APR 2021 06:10:09

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

18 APR 2021 09:12:11

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

25 APR 2021 16:10:04

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

02 MAY 2021 08:06:30

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 271

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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Patient Cloud Close Date & Time	30 SEP 2021 23:59
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US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	07 OCT 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 418

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 481

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

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

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

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

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

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

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 <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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 635

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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="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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 705

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

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

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

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

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

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

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	25 AUG 2022 23:59
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US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3232162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:09:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 07:19:41

US3232162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:52:00

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:52:00

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3232162

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:23:43

Generated On: 09 Jun 2021 16:09:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 APR 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

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:23:43

Generated On: 09 Jun 2021 16:09:18

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) _____

US3232162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:23:43

Generated On: 09 Jun 2021 16:09:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 APR 2021

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

US3232162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:23:43

Generated On: 09 Jun 2021 16:09:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 APR 2021
Collection time (00:00-23:59)	08:54 (24 HR)
Collection date and time (derived)	9 APR 2021 08:54

US3232162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:23:43

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3232162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3232162

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:09:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3232162

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3232162

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3232162

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

12:30 (24 HR)

Collection date and time (derived)

15 JAN 2021 12:30

US3232162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00 - 23:59)

12:24

Collection Date and Time (derived)

15 JAN 2021 12:24

US3232162

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:57:33

Generated On: 09 Jun 2021 16:09:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

AEID	USA-US105-2021-MRNA-1273-P30 1000005
Adverse event	ACUTE EXACERBATION OF CONGESTIVE HEART FAILURE
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)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 FEB 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	02 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	329 of 2164

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

PATIENT PRESENTED TO THE
ER ON 31JAN2021 C/O
WORSENING SOB/DOE X 2
DAYS AND PALPITATIONS.

HE WAS DIAGNOSED WITH
NEW ONSET IDIOPATHIC
DILATED CARDIOMYOPATHY
WITH ACUTE COMBINED
SYSTOLIC AND DIASTOLIC
CHF; A NEWLY DIAGNOSED
RBBB WAS ALSO NOTED.

SUBJECT WAS ADMITTED TO
THE HOSPITAL AND
UNDERWENT FURTHER
EVALUATION WITH CTA CHEST
WHICH WAS NEGATIVE FOR PE.
ECHOCARDIOGRAM REVEALED
SEVERE GLOBAL HYPOKINESIS
AND MODERATE DILATION OF
LV CHAMBER. SYMPTOMS
IMPROVED AFTER DIURESIS
WITH LASIX. PATIENT
STARTED ON ENTRESTO,
COREG AND
SPIRONOLACTONE.

CARDIOLOGY WAS
CONSULTED AND
RECOMMENDED AN
OUTPATIENT ISCHEMIC
EVALUATION. PATIENT WAS
DISCHARGED FROM THE
HOSPITAL ON 02FEB2021 WITH
A CARDIOLOGIST FOLLOW-UP
APPOINTMENT.

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

AEID

Adverse event

NEW ONSET RIGHT BUNDLE
BRANCH BLOCK

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)

31 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

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	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)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

AEID	
Adverse event	WORSENING OF DIABETES TYPE II
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

AEID	
Adverse event	WORSENER CHRONIC ESSENTIAL HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Mar 2021 14:20:41

Generated On: 09 Jun 2021 16:09:18

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
STARTED COREG 12.5MG 31JAN2021 AND WAS INCREASED TO 25MG BID ON 25FEB2021	
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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US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

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) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

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 (1)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 JAN 2021	
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 (2)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication FARXIGA

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF DIABETES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 FEB 2021	
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 (3)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication SACUBITRIL

Prophylaxis Yes ☐
No ☒

Indication ACUTE EXACERBATION OF
CONGESTIVE HEART FAILURE

Dose per administration 24

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 (3)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
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 (4)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication ACUTE EXACERBATION OF
CONGESTIVE HEART FAILURE

Dose per administration 26

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 (4)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
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 (5)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication COREG

Prophylaxis Yes ☐
No ☒

Indication WORSENEH HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 24 FEB 2021		
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 (6)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication ACUTE EXACERBATION OF
CONGESTIVE HEART FAILURE

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 (6)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (7)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication ACUTE EXACERBATION OF
CONGESTIVE HEART FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (8)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication ACUTE EXACERBATION OF
CONGESTIVE HEART FAILURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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 checked="" 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 JAN 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 JAN 2021
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 (9)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLACTIC RENAL PROTECTION

Dose per administration 50

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 (9)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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 NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 JAN 2021	
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 (10)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication SACUBITRIL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC CONGESTIVE HEART FAILURE

Dose per administration 97

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 (10)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC DIASTOLIC AND
SYSTOLIC COMBINED
CONGESTIVE HEART FAILURE

Dose per administration 103

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 (11)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Name of Medication COREG

Prophylaxis Yes ☐
No ☒

Indication WORSENERD CHRONIC
ESSENTIAL HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 JAN 2021	CTA OF CHEST WITH ECHOCARDIOGRAM	Adverse Event	

US3232162

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:09:18

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

US3232162

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:09:18

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 ☐

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/FEB/2021 12:04
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

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBKSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 09:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/FEB/2021 11:56
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

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/MAR/2021 09:56
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

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/MAR/2021 12:03
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

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 14:17:31

Generated On: 09 Jun 2021 16:09:18

SAEID	USA-US105-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/MAR/2021 10:16
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

US3232162 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232162

Form: Participant Creation

Generated On: 09 Jun 2021 16:09:18

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered 'US3232162'	(b) (4)	
	RWS_ENDPOINT	11 Sep 2020 14:39:49
	ENDPOINT (b) (4)	
	(b) (4)	

US3232162

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:20:39
	(b) (4)	

US3232162

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '11 SEP 2020'	RWS_ENDPOINT	11 Sep 2020 14:39:50
	ENDPOINT (b) (4)	
	(b) (4)	

US3232162

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	12 Sep 2020 16:20:39
	(b) (4)	

US3232162

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'SCRN'	(b) (4), (b) (6) System	12 Sep 2020 16:20:39

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered (b) (6) 1952'	RWS_ENDPOINT	11 Sep 2020 14:39:50
	ENDPOINT (b) (4)	
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '68'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'YEARS'	(b) (4), (b) (6) System	12 Sep 2020 16:21:10

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '68'	(b) (4), (b) (6) System	11 Sep 2020 15:51:42

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Male (M)'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'I'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:09:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:10
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	11 Sep 2020 15:51:42
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Sep 2020'	(b) (4), (b) (6) System	11 Sep 2020 15:51:42

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2020'	(b) (4), (b) (6) System	11 Sep 2020 15:51:42

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Amendment 3 (3)'	Adreanna Pou (b) (4)	11 Sep 2020 15:51:42
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	11 Sep 2020 15:51:42
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	11 Sep 2020 15:51:42
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	11 Sep 2020 15:51:42
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	11 Sep 2020 15:51:42
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	RWS_ENDPOINT	11 Sep 2020 14:39:50
	ENDPOINT (b) (4)	
	(b) (4)	

US3232162

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:09:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 15:51:47

US3232162

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	11 Sep 2020 15:51:47
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:09:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:21:17
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:35:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:35:36
	(b) (4)	
Data point term sent to Coder	System	12 Sep 2020 16:34:17
User entered 'MYOPIA (EYEGLASSES)'	Adreanna Pou (b) (4)	12 Sep 2020 16:33:44
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2015'	Adreanna Pou (b) (4)	12 Sep 2020 16:33:44
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:33:44
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:33:44
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:33:44
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:33:44
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2015'	(b) (4), (b) (6) System	12 Sep 2020 16:33:44

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2015'	(b) (4), (b) (6) System	12 Sep 2020 16:33:44

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	12 Sep 2020 16:33:44

US3232162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	12 Sep 2020 16:33:44

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	14 Sep 2020 16:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	14 Sep 2020 16:36:48
Data point term sent to Coder	System	14 Sep 2020 16:36:16
Coding entries removed.	Adreanna Pou (b) (4)	14 Sep 2020 16:35:22
User entered 'CATARACTS BILATERAL EYES' reason for change: New Information	(b) (4) Adreanna Pou (b) (4)	14 Sep 2020 16:35:22
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 16:35:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	12 Sep 2020 16:35:36
Data point term sent to Coder	System	12 Sep 2020 16:34:17
User entered 'CATARACTS'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:34:15

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2015'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:15
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:15
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:15
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2015'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:15
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:15
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2015'	(b) (4), (b) (6) System	12 Sep 2020 16:34:15

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2015'	(b) (4), (b) (6) System	12 Sep 2020 16:34:15

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2015'	(b) (4), (b) (6) System	12 Sep 2020 16:34:15

US3232162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2015'	(b) (4), (b) (6) System	12 Sep 2020 16:34:15

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 16:36:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:36:37
Data point term sent to Coder	System	12 Sep 2020 16:35:18
User entered 'DIVERTICULOSIS'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:34:52

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2010'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:52
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:52
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:52
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:34:52
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:34:52
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2010'	(b) (4), (b) (6) System	12 Sep 2020 16:34:52

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2010'	(b) (4), (b) (6) System	12 Sep 2020 16:34:52

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	12 Sep 2020 16:34:52

US3232162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	12 Sep 2020 16:34:52

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 16:37:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:37:37
Data point term sent to Coder	System	12 Sep 2020 16:36:21
User entered 'TYPE 2 DIABETES'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:35:43

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2015'	Adreanna Pou (b) (4)	12 Sep 2020 16:35:43
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:35:43
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 16:38:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 16:38:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	12 Sep 2020 16:38:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 16:35:43
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:35:43
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:35:43
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:35:43
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2015'	(b) (4), (b) (6) System	12 Sep 2020 16:35:43

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2015'	(b) (4), (b) (6) System	12 Sep 2020 16:35:43

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	12 Sep 2020 16:35:43

US3232162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	12 Sep 2020 16:35:43

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 16:39:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 16:39:39
Data point term sent to Coder	System	12 Sep 2020 16:38:22
User entered 'BASAL CELL SKIN CANCER'	Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:38:04

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '10 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:04
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:04
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:04
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '10 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:04
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:04
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Sep 2020'	(b) (4), (b) (6) System	12 Sep 2020 16:38:04

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2020'	(b) (4), (b) (6) System	12 Sep 2020 16:38:04

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Sep 2020'	(b) (4), (b) (6) System	12 Sep 2020 16:38:04

US3232162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2020'	(b) (4), (b) (6) System	12 Sep 2020 16:38:04

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatic operation, LLT: Prostate surgery - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:40:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 16:40:40
	(b) (4)	
Data point term sent to Coder	System	12 Sep 2020 16:39:24
User entered 'PROSTATE SURGERY'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2019'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'UN UNK 2019'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:38:38
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2019'	(b) (4), (b) (6) System	12 Sep 2020 16:38:38

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2019'	(b) (4), (b) (6) System	12 Sep 2020 16:38:38

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Jan 2019'	(b) (4), (b) (6) System	12 Sep 2020 16:38:38

US3232162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2019'	(b) (4), (b) (6) System	12 Sep 2020 16:38:38

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	11 Jan 2021 17:36:10
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'patient does not take any medication for this condition ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 15:40:42
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Jan 2021 02:27:15
User closed query 'Per MM, was the subject diagnosed with hypertension? please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 19:54:08
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 13:30:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 13:30:29

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

Condition

Audit	User	Time (GMT)
Query 'Per MM, was the subject diagnosed with hypertension? please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4)	02 Nov 2020 21:15:28
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	02 Nov 2020 21:15:04
	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:31
	(b) (4)	
User entered 'hypertension' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:31
	(b) (4)	
User opened query 'Per MM, was the subject diagnosed with hypertension? please confirm if this condition is stable and did not require significant change in therapy or hospitalization for worsening disease during 3 months before enrollment.' (Site from DM).	(b) (4), (b) (6)	-02 Oct 2020 18:44:19
	(b) (4), (b) (6)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 16:36:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 16:36:48
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 16:36:16
User entered 'HIGH BLOOD PRESSURE'	Adreanna Pou (b) (4)	14 Sep 2020 16:35:59
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	29 Mar 2021 19:03:08
Signature has been broken.	(b) (4) Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:17
User entered '01 Oct 2012' reason for change: Per Query Resolution	(b) (4) Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:17
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Oct 2020 09:11:02
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22.' answered with 'per query resolution' (Site from DM).	Adreanna Pou (b) (4) (b) (4)	28 Sep 2020 18:31:59
User entered '09 Jan 2020' reason for change: Per Query Resolution	Adreanna Pou (b) (4) (b) (4)	28 Sep 2020 18:31:50
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day please review and update as per CCGs page 22.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Sep 2020 10:36:18
User entered '11 Sep 2020'	Adreanna Pou (b) (4) (b) (4)	14 Sep 2020 16:35:59

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	14 Sep 2020 16:35:59
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	14 Sep 2020 16:35:59
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	14 Sep 2020 16:35:59
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	14 Sep 2020 16:35:59
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User entered 'Oct 2012'	System	24 Mar 2021 13:49:17
User entered 'Jan 2020'	System	28 Sep 2020 18:31:50
User entered 'Sep 2020'	System	14 Sep 2020 16:35:59

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2012'	(b) (4), (b) (6)	
	System	24 Mar 2021 13:49:17
User entered '2020'	System	14 Sep 2020 16:35:59

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 16:35:59

US3232162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	14 Sep 2020 16:35:59

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	29 Mar 2021 19:03:08
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Mar 2021 13:50:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:50:34
Data point term sent to Coder	System	24 Mar 2021 13:50:17
User entered 'benign prostatic hyperplasia'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 13:49:47

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered '04 Nov 2019'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:47
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:47
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:47
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:47
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:49:47
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'Nov 2019'	(b) (4), (b) (6) System	24 Mar 2021 13:49:47

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2019'	(b) (4), (b) (6) System	24 Mar 2021 13:49:47

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	24 Mar 2021 13:49:47

US3232162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	24 Mar 2021 13:49:47

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	29 Mar 2021 19:03:08
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 13:35:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:35:05
Data point term sent to Coder	System	24 Mar 2021 13:58:22
User entered 'chronic diastolic and systolic congestive heart failure'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 13:57:48

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered '21 May 2020'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:57:48
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:57:48
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:57:48
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 13:57:48
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	29 Mar 2021 19:03:08
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:57:48
	(b) (4)	

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'May 2020'	(b) (4), (b) (6) System	24 Mar 2021 13:57:48

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '2020'	(b) (4), (b) (6) System	24 Mar 2021 13:57:48

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	24 Mar 2021 13:57:48

US3232162

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered empty.	(b) (4), (b) (6) System	24 Mar 2021 13:57:48

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '09:58'	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '11 Sep 2020 09:58'	(b) (4), (b) (6) System	12 Sep 2020 16:22:24

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered '180' cm	(b) (4) Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
DataPoint set to visible.	(b) (4) System	11 Sep 2020 15:51:47

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '126' kg	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	
DataPoint set to visible.	System	11 Sep 2020 15:51:47

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered '38.88889'	(b) (4), (b) (6)	
	System	12 Sep 2020 16:22:24
DataPoint set to visible.	System	11 Sep 2020 15:51:47

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'kg/m2'	(b) (4), (b) (6)	12 Sep 2020 16:22:24
DataPoint set to visible.	System	11 Sep 2020 15:51:47

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'bpm'	(b) (4), (b) (6) System	12 Sep 2020 16:22:24

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Sep 2020 16:22:24

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'mmHg'	(b) (4), (b) (6) System	12 Sep 2020 16:22:24

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:24
	(b) (4)	

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'mmHg'	(b) (4), (b) (6) System	12 Sep 2020 16:22:24

US3232162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:20:42

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:20:42

US3232162

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:22:30
	(b) (4)	

US3232162

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:22:30
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 16:23:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Sep 2020 16:23:30
User entered 'No (N)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	12 Sep 2020 16:23:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Sep 2020 16:23:24
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'I'	Adreanna Pou (b) (4)	12 Sep 2020 16:23:24
	(b) (4)	

US3232162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:09:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:45
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION'	(b) (4) Adreanna Pou (b) (4) (b) (4)	12 Sep 2020 16:23:24

US3232162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:31
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	12 Sep 2020 16:28:53
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	12 Sep 2020 16:28:53
User entered '11 Sep 2020' reason for change: Data Entry Error	Adreanna Pou (b) (4)	12 Sep 2020 16:28:53
	(b) (4)	
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	12 Sep 2020 16:18:31
User entered '12 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:31
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:31
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'VISIT1'	System	12 Sep 2020 16:18:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:28:53
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Sep 2020 16:28:53
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:18:31
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 15:14:51

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '190519'	RWS_ENDPOINT	11 Sep 2020 15:14:51
	ENDPOINT (b) (4)	
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT	11 Sep 2020 15:14:51
	ENDPOINT (b) (4)	
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:20
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:20
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:20
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:18:20
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:09:18

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	01 Dec 2020 19:14:20
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:08:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:08:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:28:53
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:28:27
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '09:58'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '11 Sep 2020 09:58'	(b) (4), (b) (6)	12 Sep 2020 16:28:27
	System	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '98.3' F	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	18 Sep 2020 22:15:03
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	18 Sep 2020 22:15:03
	(b) (4)	
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	12 Sep 2020 16:28:27
User entered 'Other (Other)'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '76'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'bpm'	System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '20'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
Amendment Manager: 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	17 Sep 2020 00:33:12
Amendment Manager: 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	17 Sep 2020 00:33:12
Amendment Manager: Query text changed to "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."	System	17 Sep 2020 00:33:12
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	12 Sep 2020 16:28:27
User entered '173'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '83'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6)	12 Sep 2020 16:28:27
	System	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:09:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered missing code ND - Not Done.	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:28:53
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:28:27
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '11:20'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '11 Sep 2020 11:20'	(b) (4), (b) (6)	12 Sep 2020 16:28:27
	System	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '97.5' F	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Other (Other)'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'TEMPORAL'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '74'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'bpm'	System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '18'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
Amendment Manager: 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	17 Sep 2020 00:33:12
Amendment Manager: 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	17 Sep 2020 00:33:12
Amendment Manager: Query text changed to "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."	System	17 Sep 2020 00:33:12
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	12 Sep 2020 16:28:27
User entered '172'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '95'	Adreanna Pou (b) (4)	12 Sep 2020 16:28:27
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	12 Sep 2020 16:28:27

US3232162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:31:44
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:31:56
User entered '11 Sep 2020' reason for change: Data Entry Error	Adreanna Pou (b) (4)	12 Sep 2020 16:31:56
	(b) (4)	
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:31:44
User entered '12 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:31:44
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Sep 2020 15:52:43
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).		11 Sep 2020 15:52:43
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Sep 2020 15:52:00
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	11 Sep 2020 15:52:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	11 Sep 2020 15:52:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	11 Sep 2020 15:52:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	11 Sep 2020 15:52:00
	System	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:28:53
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Sep 2020 16:28:53
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	12 Sep 2020 16:18:31
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	11 Sep 2020 15:52:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '10:40' reason for change: Data Entry Error	Adreanna Pou (b) (4)	11 Sep 2020 16:12:56
	(b) (4)	
User entered '10:45' reason for change: Data Entry Error	Adreanna Pou (b) (4)	11 Sep 2020 15:52:43
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	11 Sep 2020 15:52:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User entered '11 Sep 2020 10:40'	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 10:45'	System	11 Sep 2020 15:52:43
User entered empty.	System	11 Sep 2020 15:52:00

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Adreanna Pou (b) (4)	11 Sep 2020 15:52:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'ONCE'	System	11 Sep 2020 15:52:00

US3232162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	11 Sep 2020 15:52:00

US3232162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:29
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:29
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '09:58'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:29
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '11 Sep 2020 09:58'	(b) (4), (b) (6)	12 Sep 2020 16:32:29
	System	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '11 Sep 2020'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '09:59'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '11 Sep 2020 09:59'	(b) (4), (b) (6)	12 Sep 2020 16:32:56
	System	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	12 Sep 2020 16:32:56
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 16:32:56
	System	

US3232162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	12 Sep 2020 16:33:00
	(b) (4)	

US3232162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	12 Sep 2020 16:33:00

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 11:00'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 11:05'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 13:30'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 13:35'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:15:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '59804787-0afb-43c2-9bc5-74b5051a25cf' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:22
	System	12 Sep 2020 00:16:22

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '59804787-0afb-43c2-9bc5-74b5051a25cf' User entered '97.5'	(b) (4), (b) (6) System	12 Sep 2020 00:16:22
	System	12 Sep 2020 00:16:22

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:13', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '59804787-0afb-43c2-9bc5-74b5051a25cf' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:22
	System	12 Sep 2020 00:16:22

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '59804787-0afb-43c2-9bc5-74b5051a25cf' User entered '11 Sep 2020 19:16'	(b) (4), (b) (6) System	12 Sep 2020 00:16:22
	System	12 Sep 2020 00:16:22

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 14:25'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 14:30'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 2'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:02', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2472786b-fd69-4112-b2f7-68c5ff6fd30e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 22:16:29
	System	12 Sep 2020 22:16:29

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:11', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2472786b-fd69-4112-b2f7-68c5ff6fd30e' User entered '98.5'	(b) (4), (b) (6) System	12 Sep 2020 22:16:29
	System	12 Sep 2020 22:16:29

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:17', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2472786b-fd69-4112-b2f7-68c5ff6fd30e'	(b) (4), (b) (6)	12 Sep 2020 22:16:29
User entered 'No (N)'	System	12 Sep 2020 22:16:29

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2472786b-fd69-4112-b2f7-68c5ff6fd30e' User entered '12 Sep 2020 17:16'	(b) (4), (b) (6) System	12 Sep 2020 22:16:29
	System	12 Sep 2020 22:16:29

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 3'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:27:46', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5c25db78-e3b4-4cb3-ad8b-5d681e5e645e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Sep 2020 23:28:11
	System	13 Sep 2020 23:28:11

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:27:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5c25db78-e3b4-4cb3-ad8b-5d681e5e645e' User entered '98.0'	(b) (4), (b) (6) System	13 Sep 2020 23:28:11
	System	13 Sep 2020 23:28:11

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5c25db78-e3b4-4cb3-ad8b-5d681e5e645e' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 23:28:11
	System	13 Sep 2020 23:28:11

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:10', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5c25db78-e3b4-4cb3-ad8b-5d681e5e645e' User entered '13 Sep 2020 18:28'	(b) (4), (b) (6) System	13 Sep 2020 23:28:11
	System	13 Sep 2020 23:28:11

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 4'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '88faaa11-a0ce-4d13-afd3-b644280aa8f0' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Sep 2020 21:03:46
	System	14 Sep 2020 21:03:46

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '88faaa11-a0ce-4d13-afd3-b644280aa8f0' User entered '97.7'	(b) (4), (b) (6) System	14 Sep 2020 21:03:46
	System	14 Sep 2020 21:03:46

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '88faaa11-a0ce-4d13-afd3-b644280aa8f0' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 21:03:46
	System	14 Sep 2020 21:03:46

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '88faaa11-a0ce-4d13-afd3-b644280aa8f0' User entered '14 Sep 2020 16:03'	(b) (4), (b) (6) System	14 Sep 2020 21:03:46
	System	14 Sep 2020 21:03:46

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 5'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T16:59:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '247100dd-6f3c-454e-98fc-0112b1fb827d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 22:00:19
	System	15 Sep 2020 22:00:19

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '247100dd-6f3c-454e-98fc-0112b1fb827d' User entered '97.7'	(b) (4), (b) (6) System	15 Sep 2020 22:00:19
	System	15 Sep 2020 22:00:19

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:13', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '247100dd-6f3c-454e-98fc-0112b1fb827d' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 22:00:19
	System	15 Sep 2020 22:00:19

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '247100dd-6f3c-454e-98fc-0112b1fb827d' User entered '15 Sep 2020 17:00'	(b) (4), (b) (6) System	15 Sep 2020 22:00:19
	System	15 Sep 2020 22:00:19

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 6'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:42:54', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '158650d6-8ef4-491f-af49-0c6451b9951c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 22:43:13
	System	16 Sep 2020 22:43:13

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '158650d6-8ef4-491f-af49-0c6451b9951c' User entered '97.4'	(b) (4), (b) (6) System	16 Sep 2020 22:43:13
	System	16 Sep 2020 22:43:13

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '158650d6-8ef4-491f-af49-0c6451b9951c' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:43:13
	System	16 Sep 2020 22:43:13

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:10', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '158650d6-8ef4-491f-af49-0c6451b9951c' User entered '16 Sep 2020 17:43'	(b) (4), (b) (6) System	16 Sep 2020 22:43:13
	System	16 Sep 2020 22:43:13

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 7'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:57:52', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2e57f940-d3ba-4a2d-bfbe-b0efdc1fcfaf'	(b) (4), (b) (6)	17 Sep 2020 17:58:15
User entered 'Yes (Y)'	System	17 Sep 2020 17:58:15

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2e57f940-d3ba-4a2d-bfbe-b0efdc1fcfaf' User entered '97.7'	(b) (4), (b) (6) System	17 Sep 2020 17:58:15
	System	17 Sep 2020 17:58:15

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2e57f940-d3ba-4a2d-bfbe-b0efdc1fcfaf'	(b) (4), (b) (6)	17 Sep 2020 17:58:15
User entered 'No (N)'	System	17 Sep 2020 17:58:15

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2e57f940-d3ba-4a2d-bfbe-b0efdc1fcfaf'	(b) (4), (b) (6) System	17 Sep 2020 17:58:15
User entered '17 Sep 2020 12:58'	System	17 Sep 2020 17:58:15

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 11:00'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 11:05'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
User entered '11 Sep 2020 13:30'	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 13:35'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:31', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '23f78633-eb9c-46af-b7ee-1aaa96572c95'	(b) (4), (b) (6)	12 Sep 2020 00:16:56
User entered 'None (1)'	System	12 Sep 2020 00:16:56

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:34', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '23f78633-eb9c-46af-b7ee-1aaa96572c95'	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Sep 2020 00:16:56

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:38', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '23f78633-eb9c-46af-b7ee-1aaa96572c95'	(b) (4), (b) (6) System	12 Sep 2020 00:16:56
User entered 'No (N)'	System	12 Sep 2020 00:16:56

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:48', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '23f78633-eb9c-46af-b7ee-1aaa96572c95'	(b) (4), (b) (6)	12 Sep 2020 00:16:56
User entered 'None (1)'	System	12 Sep 2020 00:16:56

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:52', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '23f78633-eb9c-46af-b7ee-1aaa96572c95'	(b) (4), (b) (6) System	12 Sep 2020 00:16:56
User entered '11 Sep 2020 19:16'	System	12 Sep 2020 00:16:56

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 14:25'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 14:30'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 2'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2038750a-8ee0-4997-9ee0-bda31e1c6af7'	(b) (4), (b) (6) System	12 Sep 2020 22:17:02
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:17:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:44', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2038750a-8ee0-4997-9ee0-bda31e1c6af7' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:02
	System	12 Sep 2020 22:17:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:51', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2038750a-8ee0-4997-9ee0-bda31e1c6af7' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:02
	System	12 Sep 2020 22:17:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:16:56', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2038750a-8ee0-4997-9ee0-bda31e1c6af7' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:02
	System	12 Sep 2020 22:17:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:00', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2038750a-8ee0-4997-9ee0-bda31e1c6af7' User entered '12 Sep 2020 17:17'	(b) (4), (b) (6) System	12 Sep 2020 22:17:02
	System	12 Sep 2020 22:17:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 3'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5921d162-fe51-46ce-b6f0-fa5485c6c271' User entered 'None (1)'	(b) (4), (b) (6) System	13 Sep 2020 23:28:33
	System	13 Sep 2020 23:28:33

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5921d162-fe51-46ce-b6f0-fa5485c6c271' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 23:28:33
	System	13 Sep 2020 23:28:33

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5921d162-fe51-46ce-b6f0-fa5485c6c271' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 23:28:33
	System	13 Sep 2020 23:28:33

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:26', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5921d162-fe51-46ce-b6f0-fa5485c6c271' User entered 'None (1)'	(b) (4), (b) (6) System	13 Sep 2020 23:28:33
	System	13 Sep 2020 23:28:33

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5921d162-fe51-46ce-b6f0-fa5485c6c271' User entered '13 Sep 2020 18:28'	(b) (4), (b) (6) System	13 Sep 2020 23:28:33
	System	13 Sep 2020 23:28:33

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 4'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:49', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f63579de-fdd9-47cd-8069-5bb83c2472dc' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:02
	System	14 Sep 2020 21:04:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:52', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f63579de-fdd9-47cd-8069-5bb83c2472dc' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:02
	System	14 Sep 2020 21:04:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f63579de-fdd9-47cd-8069-5bb83c2472dc' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:02
	System	14 Sep 2020 21:04:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:03:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f63579de-fdd9-47cd-8069-5bb83c2472dc' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:02
	System	14 Sep 2020 21:04:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f63579de-fdd9-47cd-8069-5bb83c2472dc' User entered '14 Sep 2020 16:04'	(b) (4), (b) (6) System	14 Sep 2020 21:04:02
	System	14 Sep 2020 21:04:02

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 5'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '39fa9feb-d1b7-4f4f-b992-e9ac664bf38b'	(b) (4), (b) (6)	15 Sep 2020 22:00:51
User entered 'None (1)'	System	15 Sep 2020 22:00:51

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:26', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '39fa9feb-d1b7-4f4f-b992-e9ac664bf38b' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 22:00:51
	System	15 Sep 2020 22:00:51

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:37', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '39fa9feb-d1b7-4f4f-b992-e9ac664bf38b' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 22:00:51
	System	15 Sep 2020 22:00:51

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:42', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '39fa9feb-d1b7-4f4f-b992-e9ac664bf38b'	(b) (4), (b) (6)	15 Sep 2020 22:00:51
User entered 'None (1)'	System	15 Sep 2020 22:00:51

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:48', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '39fa9feb-d1b7-4f4f-b992-e9ac664bf38b' User entered '15 Sep 2020 17:00'	(b) (4), (b) (6) System	15 Sep 2020 22:00:51
	System	15 Sep 2020 22:00:51

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 6'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:18', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '560e78bf-d863-4247-87ba-bc61130f76b8' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 22:43:34
	System	16 Sep 2020 22:43:34

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '560e78bf-d863-4247-87ba-bc61130f76b8' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:43:34
	System	16 Sep 2020 22:43:34

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '560e78bf-d863-4247-87ba-bc61130f76b8' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:43:34
	System	16 Sep 2020 22:43:34

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:28', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '560e78bf-d863-4247-87ba-bc61130f76b8' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 22:43:34
	System	16 Sep 2020 22:43:34

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:32', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '560e78bf-d863-4247-87ba-bc61130f76b8' User entered '16 Sep 2020 17:43'	(b) (4), (b) (6) System	16 Sep 2020 22:43:34
	System	16 Sep 2020 22:43:34

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 7'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:17', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fd394767-fa07-45ae-9142-951a95e96e51' User entered 'None (1)'	(b) (4), (b) (6) System	17 Sep 2020 17:58:36
	System	17 Sep 2020 17:58:36

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:20', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fd394767-fa07-45ae-9142-951a95e96e51' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:58:36
	System	17 Sep 2020 17:58:36

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:26', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fd394767-fa07-45ae-9142-951a95e96e51' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:58:36
	System	17 Sep 2020 17:58:36

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:29', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fd394767-fa07-45ae-9142-951a95e96e51' User entered 'None (1)'	(b) (4), (b) (6) System	17 Sep 2020 17:58:36
	System	17 Sep 2020 17:58:36

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fd394767-fa07-45ae-9142-951a95e96e51' User entered '17 Sep 2020 12:58'	(b) (4), (b) (6) System	17 Sep 2020 17:58:36
	System	17 Sep 2020 17:58:36

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:16:53

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 11:00'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 11:05'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 13:30'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 13:35'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:16:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:03', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:11', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:21', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:27', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-11T19:17:31', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'a86ddaa0-1da8-4b9f-9dc0-5ba45cdb913d' User entered '11 Sep 2020 19:17'	(b) (4), (b) (6) System	12 Sep 2020 00:17:35
	System	12 Sep 2020 00:17:35

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Sep 2020 14:25'	(b) (4), (b) (6)	
	System	11 Sep 2020 16:12:56
User entered '11 Sep 2020 14:30'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 2'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:08', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e'	(b) (4), (b) (6)	12 Sep 2020 22:17:54
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-12T17:17:50', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'b4134f87-3813-401c-85b4-fa9936dd323e' User entered '12 Sep 2020 17:17'	(b) (4), (b) (6) System	12 Sep 2020 22:17:54
	System	12 Sep 2020 22:17:54

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
Data entry locked.	(b) (4), (b) (6)	
	System	11 Sep 2020 15:52:43
User entered 'Day 3'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:35', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:39', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:42', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:44', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:47', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:49', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:52', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-13T18:28:56', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0f8d695f-8d09-433b-a707-48acbfee7a4e' User entered '13 Sep 2020 18:28'	(b) (4), (b) (6) System	13 Sep 2020 23:29:00
	System	13 Sep 2020 23:29:00

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 4'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:11', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:13', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:17', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-14T16:04:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7c777e36-5f24-49a2-8542-d84036dfce80' User entered '14 Sep 2020 16:04'	(b) (4), (b) (6) System	14 Sep 2020 21:04:28
	System	14 Sep 2020 21:04:28

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 5'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:00:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:01:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:01:04', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:01:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:01:10', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:01:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-15T17:01:18', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '31ce29e3-f7c8-42e7-b261-4690d1482837' User entered '15 Sep 2020 17:01'	(b) (4), (b) (6) System	15 Sep 2020 22:01:21
	System	15 Sep 2020 22:01:21

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 6'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:43:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:44:00', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:44:03', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-16T17:44:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '3d326bcf-423a-4810-bb50-d220e5196ed4' User entered '16 Sep 2020 17:44'	(b) (4), (b) (6) System	16 Sep 2020 22:44:09
	System	16 Sep 2020 22:44:09

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 7'	System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:48', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:51', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:58:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:59:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:59:03', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:59:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:59:08', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-09-17T12:59:11', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09606add-1147-4293-94db-de596d657002' User entered '17 Sep 2020 12:59'	(b) (4), (b) (6) System	17 Sep 2020 17:59:26
	System	17 Sep 2020 17:59:26

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 15:52:43

US3232162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	18 Sep 2020 22:14:33
	(b) (4)	

US3232162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '18 Sep 2020'	Jerrica Sullivan (b) (4)	18 Sep 2020 22:14:33
	(b) (4)	

US3232162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	18 Sep 2020 22:14:33
	(b) (4)	

US3232162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	18 Sep 2020 22:14:33
	(b) (4)	

US3232162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	18 Sep 2020 22:14:37
	(b) (4)	

US3232162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	18 Sep 2020 22:14:37

US3232162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 22:23:00
	(b) (4)	

US3232162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '25 Sep 2020'	Adreanna Pou (b) (4)	25 Sep 2020 22:23:00
	(b) (4)	

US3232162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	25 Sep 2020 22:23:00
	(b) (4)	

US3232162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	25 Sep 2020 22:23:00
	(b) (4)	

US3232162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	25 Sep 2020 22:23:04
	(b) (4)	

US3232162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	25 Sep 2020 22:23:04

US3232162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Oct 2020 16:00:47
	(b) (4)	

US3232162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '2 Oct 2020'	Adreanna Pou (b) (4)	05 Oct 2020 16:00:47
	(b) (4)	

US3232162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Adreanna Pou (b) (4)	05 Oct 2020 16:00:47
	(b) (4)	

US3232162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	05 Oct 2020 16:00:47
	(b) (4)	

US3232162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	05 Oct 2020 16:00:50
	(b) (4)	

US3232162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	05 Oct 2020 16:00:50

US3232162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 15:14:30
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 15:14:30
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	09 Oct 2020 15:14:30
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'VISIT2'	System	09 Oct 2020 15:14:30

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '09:04'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '9 Oct 2020 09:04'	(b) (4), (b) (6)	09 Oct 2020 17:54:18
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '98' F	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Oral (Oral)'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '74'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'bpm'	System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '20'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '178'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '90'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	09 Oct 2020 17:56:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4)	09 Oct 2020 17:56:18
	(b) (4)	
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	09 Oct 2020 17:54:18
User entered 'No (N)'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '10:24'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '9 Oct 2020 10:24'	(b) (4), (b) (6)	09 Oct 2020 17:54:18
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '98.1' F	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Other (Other)'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'temporal'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '68'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'bpm'	System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '22'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '154'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6)	09 Oct 2020 17:54:18
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '79'	Adreanna Pou (b) (4)	09 Oct 2020 17:54:18
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 17:54:18

US3232162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 15:15:26
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 15:15:26
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 15:15:07
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 15:15:07
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 15:15:07
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	09 Oct 2020 15:15:07
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 15:15:07
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '10:08'	Adreanna Pou (b) (4)	09 Oct 2020 15:15:07
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '9 Oct 2020 10:08'	(b) (4), (b) (6)	09 Oct 2020 15:15:07
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Adreanna Pou (b) (4)	09 Oct 2020 15:15:07
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'ONCE'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:09:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 17:56:41
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 17:56:41
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '09:15' reason for change: Data Entry Error	Adreanna Pou (b) (4)	09 Oct 2020 17:58:08
	(b) (4)	
User entered '12:10'	Adreanna Pou (b) (4)	09 Oct 2020 17:56:41
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User entered '9 Oct 2020 09:15'	System	09 Oct 2020 17:58:08
User entered '9 Oct 2020 12:10'	System	09 Oct 2020 17:56:41

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9 Oct 2020'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '09:10'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '9 Oct 2020 09:10'	(b) (4), (b) (6)	09 Oct 2020 17:58:24
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	09 Oct 2020 17:58:24
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:58:24
	System	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	09 Oct 2020 17:58:30
	(b) (4)	

US3232162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	09 Oct 2020 17:58:30

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '22faf690-df0c-4a58-a3c9-74c6a0e67f50'	(b) (4), (b) (6)	09 Oct 2020 15:29:22
User entered 'Yes (Y)'	System	09 Oct 2020 15:29:22

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '22faf690-df0c-4a58-a3c9-74c6a0e67f50' User entered '98.1'	(b) (4), (b) (6) System	09 Oct 2020 15:29:22
	System	09 Oct 2020 15:29:22

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '22faf690-df0c-4a58-a3c9-74c6a0e67f50'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Oct 2020 15:29:22

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:20', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '22faf690-df0c-4a58-a3c9-74c6a0e67f50' User entered '09 Oct 2020 10:29'	(b) (4), (b) (6) System	09 Oct 2020 15:29:22
	System	09 Oct 2020 15:29:22

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 10:28'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 12:58'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:12:23', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c2a35b9b-707d-4a7c-95f8-d7262ce136b7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Oct 2020 23:12:46
	System	09 Oct 2020 23:12:46

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:12:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c2a35b9b-707d-4a7c-95f8-d7262ce136b7' User entered '97.8'	(b) (4), (b) (6) System	09 Oct 2020 23:12:46
	System	09 Oct 2020 23:12:46

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:12:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c2a35b9b-707d-4a7c-95f8-d7262ce136b7' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 23:12:46
	System	09 Oct 2020 23:12:46

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:12:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c2a35b9b-707d-4a7c-95f8-d7262ce136b7' User entered '09 Oct 2020 18:12'	(b) (4), (b) (6) System	09 Oct 2020 23:12:46
	System	09 Oct 2020 23:12:46

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 13:53'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 2'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:38:54', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9369662-2ec1-4362-90d0-1f19672441f9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Oct 2020 21:39:10
	System	10 Oct 2020 21:39:10

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:00', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9369662-2ec1-4362-90d0-1f19672441f9' User entered '98.5'	(b) (4), (b) (6) System	10 Oct 2020 21:39:10
	System	10 Oct 2020 21:39:10

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:03', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9369662-2ec1-4362-90d0-1f19672441f9' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 21:39:10
	System	10 Oct 2020 21:39:10

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:08', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9369662-2ec1-4362-90d0-1f19672441f9' User entered '10 Oct 2020 16:39'	(b) (4), (b) (6) System	10 Oct 2020 21:39:10
	System	10 Oct 2020 21:39:10

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 3'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:19:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ff7586e8-e8fc-417e-9a3c-06b86bd29b8c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Oct 2020 02:19:50
	System	12 Oct 2020 02:19:50

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:19:39', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ff7586e8-e8fc-417e-9a3c-06b86bd29b8c' User entered '97.6'	(b) (4), (b) (6) System	12 Oct 2020 02:19:50
	System	12 Oct 2020 02:19:50

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:19:42', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ff7586e8-e8fc-417e-9a3c-06b86bd29b8c'	(b) (4), (b) (6)	
	System	12 Oct 2020 02:19:50
User entered 'No (N)'	System	12 Oct 2020 02:19:50

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:19:47', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ff7586e8-e8fc-417e-9a3c-06b86bd29b8c' User entered '11 Oct 2020 21:19'	(b) (4), (b) (6) System	12 Oct 2020 02:19:50
	System	12 Oct 2020 02:19:50

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 4'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:14', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '900ec783-5964-4151-acb8-a755ef9dece2' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Oct 2020 23:27:29
	System	12 Oct 2020 23:27:29

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:20', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '900ec783-5964-4151-acb8-a755ef9dece2' User entered '97.4'	(b) (4), (b) (6) System	12 Oct 2020 23:27:29
	System	12 Oct 2020 23:27:29

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '900ec783-5964-4151-acb8-a755ef9dece2'	(b) (4), (b) (6)	12 Oct 2020 23:27:29
User entered 'No (N)'	System	12 Oct 2020 23:27:29

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:27', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '900ec783-5964-4151-acb8-a755ef9dece2' User entered '12 Oct 2020 18:27'	(b) (4), (b) (6) System	12 Oct 2020 23:27:29
	System	12 Oct 2020 23:27:29

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 5'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'adcd4fdb-0157-493d-85b4-111cc04025ce' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Oct 2020 22:34:35
	System	13 Oct 2020 22:34:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:26', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'adcd4fdb-0157-493d-85b4-111cc04025ce' User entered '97.0'	(b) (4), (b) (6) System	13 Oct 2020 22:34:35
	System	13 Oct 2020 22:34:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'adcd4fdb-0157-493d-85b4-111cc04025ce' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 22:34:35
	System	13 Oct 2020 22:34:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'adcd4fdb-0157-493d-85b4-111cc04025ce' User entered '13 Oct 2020 17:34'	(b) (4), (b) (6) System	13 Oct 2020 22:34:35
	System	13 Oct 2020 22:34:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 6'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '27978a61-3142-4321-9e13-d0c247cfae58' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Oct 2020 22:38:35
	System	14 Oct 2020 22:38:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '27978a61-3142-4321-9e13-d0c247cfae58' User entered '97.7'	(b) (4), (b) (6) System	14 Oct 2020 22:38:35
	System	14 Oct 2020 22:38:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:28', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '27978a61-3142-4321-9e13-d0c247cfae58'	(b) (4), (b) (6)	14 Oct 2020 22:38:35
User entered 'No (N)'	System	14 Oct 2020 22:38:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:31', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '27978a61-3142-4321-9e13-d0c247cfae58' User entered '14 Oct 2020 17:38'	(b) (4), (b) (6) System	14 Oct 2020 22:38:35
	System	14 Oct 2020 22:38:35

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 7'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:38:47', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e545302c-1acb-4eff-92f8-d6d569d96795'	(b) (4), (b) (6)	
	System	15 Oct 2020 22:39:07
User entered 'Yes (Y)'	System	15 Oct 2020 22:39:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:38:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e545302c-1acb-4eff-92f8-d6d569d96795' User entered '98.0'	(b) (4), (b) (6) System	15 Oct 2020 22:39:07
	System	15 Oct 2020 22:39:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:02', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e545302c-1acb-4eff-92f8-d6d569d96795'	(b) (4), (b) (6)	
	System	15 Oct 2020 22:39:07
User entered 'No (N)'	System	15 Oct 2020 22:39:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e545302c-1acb-4eff-92f8-d6d569d96795' User entered '15 Oct 2020 17:39'	(b) (4), (b) (6) System	15 Oct 2020 22:39:07
	System	15 Oct 2020 22:39:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:29', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '30de86a3-8c7c-4531-b141-8440337ccf2c' User entered 'None (1)'	(b) (4), (b) (6) System	09 Oct 2020 15:29:53
	System	09 Oct 2020 15:29:53

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:34', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '30de86a3-8c7c-4531-b141-8440337ccf2c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 15:29:53
	System	09 Oct 2020 15:29:53

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '30de86a3-8c7c-4531-b141-8440337ccf2c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 15:29:53
	System	09 Oct 2020 15:29:53

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '30de86a3-8c7c-4531-b141-8440337ccf2c' User entered 'None (1)'	(b) (4), (b) (6) System	09 Oct 2020 15:29:53
	System	09 Oct 2020 15:29:53

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:51', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '30de86a3-8c7c-4531-b141-8440337ccf2c' User entered '09 Oct 2020 10:29'	(b) (4), (b) (6) System	09 Oct 2020 15:29:53
	System	09 Oct 2020 15:29:53

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 10:28'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 12:58'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8b226cf3-8963-412c-8e7d-7fc4b99d1de9'	(b) (4), (b) (6) System	09 Oct 2020 23:13:29
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 23:13:29

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:11', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8b226cf3-8963-412c-8e7d-7fc4b99d1de9' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 23:13:29
	System	09 Oct 2020 23:13:29

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8b226cf3-8963-412c-8e7d-7fc4b99d1de9' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 23:13:29
	System	09 Oct 2020 23:13:29

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8b226cf3-8963-412c-8e7d-7fc4b99d1de9' User entered 'None (1)'	(b) (4), (b) (6) System	09 Oct 2020 23:13:29
	System	09 Oct 2020 23:13:29

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:27', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8b226cf3-8963-412c-8e7d-7fc4b99d1de9' User entered '09 Oct 2020 18:13'	(b) (4), (b) (6) System	09 Oct 2020 23:13:29
	System	09 Oct 2020 23:13:29

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 13:53'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 2'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '1b4f9d2d-3875-42b6-ad95-3c859697e0b4'	(b) (4), (b) (6)	10 Oct 2020 21:39:46
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 21:39:46

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:27', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '1b4f9d2d-3875-42b6-ad95-3c859697e0b4' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 21:39:46
	System	10 Oct 2020 21:39:46

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:31', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '1b4f9d2d-3875-42b6-ad95-3c859697e0b4' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 21:39:46
	System	10 Oct 2020 21:39:46

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:39', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '1b4f9d2d-3875-42b6-ad95-3c859697e0b4' User entered 'None (1)'	(b) (4), (b) (6) System	10 Oct 2020 21:39:46
	System	10 Oct 2020 21:39:46

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '1b4f9d2d-3875-42b6-ad95-3c859697e0b4' User entered '10 Oct 2020 16:39'	(b) (4), (b) (6) System	10 Oct 2020 21:39:46
	System	10 Oct 2020 21:39:46

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 3'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '418ba623-f1ea-4b40-8098-5218a7d2fed0' User entered 'None (1)'	(b) (4), (b) (6) System	12 Oct 2020 02:20:22
	System	12 Oct 2020 02:20:22

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '418ba623-f1ea-4b40-8098-5218a7d2fed0' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 02:20:22
	System	12 Oct 2020 02:20:22

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:10', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '418ba623-f1ea-4b40-8098-5218a7d2fed0' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 02:20:22
	System	12 Oct 2020 02:20:22

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '418ba623-f1ea-4b40-8098-5218a7d2fed0' User entered 'None (1)'	(b) (4), (b) (6) System	12 Oct 2020 02:20:22
	System	12 Oct 2020 02:20:22

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:21', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '418ba623-f1ea-4b40-8098-5218a7d2fed0' User entered '11 Oct 2020 21:20'	(b) (4), (b) (6) System	12 Oct 2020 02:20:22
	System	12 Oct 2020 02:20:22

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 4'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:32', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de12298-7210-46cf-8e6a-4036c350bc66' User entered 'None (1)'	(b) (4), (b) (6) System	12 Oct 2020 23:27:47
	System	12 Oct 2020 23:27:47

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:35', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de12298-7210-46cf-8e6a-4036c350bc66' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 23:27:47
	System	12 Oct 2020 23:27:47

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:37', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de12298-7210-46cf-8e6a-4036c350bc66' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 23:27:47
	System	12 Oct 2020 23:27:47

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de12298-7210-46cf-8e6a-4036c350bc66'	(b) (4), (b) (6)	12 Oct 2020 23:27:47
User entered 'None (1)'	System	12 Oct 2020 23:27:47

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de12298-7210-46cf-8e6a-4036c350bc66' User entered '12 Oct 2020 18:27'	(b) (4), (b) (6) System	12 Oct 2020 23:27:47
	System	12 Oct 2020 23:27:47

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 5'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:38', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '29a5db9a-1f14-4369-8ef5-f0aea8f3e375' User entered 'None (1)'	(b) (4), (b) (6) System	13 Oct 2020 22:34:50
	System	13 Oct 2020 22:34:50

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '29a5db9a-1f14-4369-8ef5-f0aea8f3e375' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 22:34:50
	System	13 Oct 2020 22:34:50

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '29a5db9a-1f14-4369-8ef5-f0aea8f3e375' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 22:34:50
	System	13 Oct 2020 22:34:50

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:46', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '29a5db9a-1f14-4369-8ef5-f0aea8f3e375' User entered 'None (1)'	(b) (4), (b) (6) System	13 Oct 2020 22:34:50
	System	13 Oct 2020 22:34:50

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:34:49', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '29a5db9a-1f14-4369-8ef5-f0aea8f3e375' User entered '13 Oct 2020 17:34'	(b) (4), (b) (6) System	13 Oct 2020 22:34:50
	System	13 Oct 2020 22:34:50

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 6'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:35', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'cf52160b-486a-436b-b4bc-ce30f1a1dc41' User entered 'None (1)'	(b) (4), (b) (6) System	14 Oct 2020 22:38:55
	System	14 Oct 2020 22:38:55

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:38', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'cf52160b-486a-436b-b4bc-ce30f1a1dc41' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 22:38:55
	System	14 Oct 2020 22:38:55

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'cf52160b-486a-436b-b4bc-ce30f1a1dc41' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 22:38:55
	System	14 Oct 2020 22:38:55

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'cf52160b-486a-436b-b4bc-ce30f1a1dc41' User entered 'None (1)'	(b) (4), (b) (6) System	14 Oct 2020 22:38:55
	System	14 Oct 2020 22:38:55

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:52', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'cf52160b-486a-436b-b4bc-ce30f1a1dc41' User entered '14 Oct 2020 17:38'	(b) (4), (b) (6) System	14 Oct 2020 22:38:55
	System	14 Oct 2020 22:38:55

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 7'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:10', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '135bf034-c757-4091-b174-38fd1bbff813'	(b) (4), (b) (6)	15 Oct 2020 22:39:28
User entered 'None (1)'	System	15 Oct 2020 22:39:28

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '135bf034-c757-4091-b174-38fd1bbff813' User entered 'No (N)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:28
	System	15 Oct 2020 22:39:28

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '135bf034-c757-4091-b174-38fd1bbff813' User entered 'No (N)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:28
	System	15 Oct 2020 22:39:28

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:21', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '135bf034-c757-4091-b174-38fd1bbff813'	(b) (4), (b) (6)	15 Oct 2020 22:39:28
User entered 'None (1)'	System	15 Oct 2020 22:39:28

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '135bf034-c757-4091-b174-38fd1bbff813' User entered '15 Oct 2020 17:39'	(b) (4), (b) (6) System	15 Oct 2020 22:39:28
	System	15 Oct 2020 22:39:28

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:57', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:29:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:30:02', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:30:06', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:30:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:30:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:30:34', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T10:30:39', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2ef86086-9190-4a18-aa95-9b96850fb42b' User entered '09 Oct 2020 10:30'	(b) (4), (b) (6) System	09 Oct 2020 15:30:43
	System	09 Oct 2020 15:30:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 10:28'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 12:58'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:34', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 23:14:16
	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:46', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97'	(b) (4), (b) (6)	
	System	09 Oct 2020 23:14:16
User entered 'No interference with activity (1)'	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:49', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97'	(b) (4), (b) (6)	
	System	09 Oct 2020 23:14:16
User entered 'No interference with activity (1)'	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 23:14:16
	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:13:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 23:14:16
	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:14:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 23:14:16
	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:14:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 23:14:16
	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-09T18:14:08', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '96eb097e-57fa-4c7e-a497-36642f4acc97' User entered '09 Oct 2020 18:14'	(b) (4), (b) (6) System	09 Oct 2020 23:14:16
	System	09 Oct 2020 23:14:16

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '09 Oct 2020 13:53'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 2'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:39:53', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:00', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:14', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:17', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered 'No (N)'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-10T16:40:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '65e2867a-55be-4792-9ee2-7fb124d5758a' User entered '10 Oct 2020 16:40'	(b) (4), (b) (6) System	10 Oct 2020 21:40:28
	System	10 Oct 2020 21:40:28

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 3'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:29', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
User entered 'No interference with activity (1)'	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229'	(b) (4), (b) (6)	12 Oct 2020 02:21:00
User entered 'No interference with activity (1)'	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:44', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:47', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:50', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:54', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-11T21:20:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab42947-8f14-43ce-b530-d89d9b4b1229' User entered '11 Oct 2020 21:20'	(b) (4), (b) (6) System	12 Oct 2020 02:21:00
	System	12 Oct 2020 02:21:00

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 4'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:53', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:27:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:28:03', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:28:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:28:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:28:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:28:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered 'No (N)'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-12T18:28:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '40d1457e-30c7-4a6f-94f8-def79c156161' User entered '12 Oct 2020 18:28'	(b) (4), (b) (6) System	12 Oct 2020 23:28:18
	System	12 Oct 2020 23:28:18

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 5'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:18', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'None (0)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:39', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered 'No (N)'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-13T17:35:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '93105cfb-bc11-4ffc-bc0f-cbdcb98ba7b2' User entered '13 Oct 2020 17:35'	(b) (4), (b) (6) System	13 Oct 2020 22:35:43
	System	13 Oct 2020 22:35:43

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 6'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:38:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:03', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-14T17:39:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '2f091c79-9c88-4f0e-83b9-7db17a9de693' User entered '14 Oct 2020 17:39'	(b) (4), (b) (6) System	14 Oct 2020 22:39:19
	System	14 Oct 2020 22:39:19

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	09 Oct 2020 15:15:07
User entered 'Day 7'	System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:29', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:38', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'None (0)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:51', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered 'No (N)'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-10-15T17:39:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4c70bef3-1742-44b3-b37f-52f0f5cf5513' User entered '15 Oct 2020 17:39'	(b) (4), (b) (6) System	15 Oct 2020 22:39:57
	System	15 Oct 2020 22:39:57

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:09:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	09 Oct 2020 15:15:07

US3232162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	17 Oct 2020 12:39:45
	(b) (4)	

US3232162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '16 Oct 2020'	Jerrica Sullivan (b) (4)	17 Oct 2020 12:39:45
	(b) (4)	

US3232162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	17 Oct 2020 12:39:45
	(b) (4)	

US3232162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	17 Oct 2020 12:39:45
	(b) (4)	

US3232162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	17 Oct 2020 12:39:38
	(b) (4)	

US3232162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	17 Oct 2020 12:39:38

US3232162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Oct 2020 13:29:02
	(b) (4)	

US3232162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '23 Oct 2020'	Jerrica Sullivan (b) (4)	26 Oct 2020 13:29:02
	(b) (4)	

US3232162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	26 Oct 2020 13:29:02
	(b) (4)	

US3232162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	26 Oct 2020 13:29:02
	(b) (4)	

US3232162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	26 Oct 2020 13:29:08
	(b) (4)	

US3232162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 13:29:08
	System	

US3232162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:04
	(b) (4)	

US3232162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered '2 Nov 2020'	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:04
	(b) (4)	

US3232162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:04
	(b) (4)	

US3232162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:04
	(b) (4)	

US3232162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:11:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	02 Nov 2020 21:14:10
	(b) (4)	

US3232162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	02 Nov 2020 21:14:10

US3232162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:04:27
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '6 Nov 2020'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:04:27
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Clinic (Clinic)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:04:27
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'VISIT3'	System	06 Nov 2020 16:04:27

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '6 Nov 2020'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '8:55'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '6 Nov 2020 8:55'	(b) (4), (b) (6)	06 Nov 2020 16:06:39
	System	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '97.7' F	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Oral (Oral)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '73'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'bpm'	System	06 Nov 2020 16:06:39

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'breaths/min'	(b) (4), (b) (6)	06 Nov 2020 16:06:39
	System	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '169'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	06 Nov 2020 16:06:39

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '84'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:06:39
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'mmHg'	(b) (4), (b) (6) System	06 Nov 2020 16:06:39

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:05:02
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '6 Nov 2020'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:05:02
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:07:00
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '6 Nov 2020'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:07:00
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered '9:02'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:07:00
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered '6 Nov 2020 9:02'	(b) (4), (b) (6)	06 Nov 2020 16:07:00
	System	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	18 Feb 2021 16:12:12
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	06 Nov 2020 16:04:33
	(b) (4)	

US3232162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	06 Nov 2020 16:04:33

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 64'	System	11 Sep 2020 15:52:43

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-14T07:00:42', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09122baa-22b0-431f-993c-5189e6ec7e7d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Nov 2020 13:00:58
	System	14 Nov 2020 13:00:58

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-14T07:00:46', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09122baa-22b0-431f-993c-5189e6ec7e7d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Nov 2020 13:00:58
	System	14 Nov 2020 13:00:58

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-14T07:00:53', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '09122baa-22b0-431f-993c-5189e6ec7e7d' User entered '14 Nov 2020 07:00:53'	(b) (4), (b) (6) System	14 Nov 2020 13:00:58
	System	14 Nov 2020 13:00:58

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 15:52:43

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:53
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 15:52:43
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 15:52:43

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45
Data entry locked.	System	11 Sep 2020 15:52:43
User entered 'Day 71'	System	11 Sep 2020 15:52:43

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45
Data entry locked.	System	11 Sep 2020 15:52:43
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 15:52:43

US3232162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:45
Data entry locked.	System	11 Sep 2020 15:52:43
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 15:52:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-22T11:26:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ee5b166e-ad2f-426d-98d6-1e75708f3111' User entered 'No (N)'	System	22 Nov 2020 17:26:49

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-22T11:26:37', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ee5b166e-ad2f-426d-98d6-1e75708f3111' User entered 'No (N)'	System	22 Nov 2020 17:26:49

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-22T11:26:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ee5b166e-ad2f-426d-98d6-1e75708f3111' User entered '22 Nov 2020 11:26:45'	System	22 Nov 2020 17:26:49

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-29T11:12:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ca29c3f7-2b18-4190-937c-58c1f3d30f8e' User entered 'No (N)'	System	29 Nov 2020 17:12:39

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-29T11:12:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ca29c3f7-2b18-4190-937c-58c1f3d30f8e'	System	29 Nov 2020 17:12:39
User entered 'No (N)'	System	29 Nov 2020 17:12:39

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-11-29T11:12:37', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'ca29c3f7-2b18-4190-937c-58c1f3d30f8e' User entered '29 Nov 2020 11:12:37'	System	29 Nov 2020 17:12:39

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-12-10T17:20:32', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '62b232d6-6bac-4741-add3-65e48bf6ab2a' User entered 'No (N)'	System	10 Dec 2020 23:20:54
	System	10 Dec 2020 23:20:54

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Have you been exposed to someone with 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 (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-12-10T17:20:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '62b232d6-6bac-4741-add3-65e48bf6ab2a' User entered 'No (N)'	System	10 Dec 2020 23:20:54
	System	10 Dec 2020 23:20:54

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22EA3408-375A-4F91-96EB-D7A0F55691C7)', Time: '2020-12-10T17:20:50', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '62b232d6-6bac-4741-add3-65e48bf6ab2a' User entered '10 Dec 2020 17:20:50'	System	10 Dec 2020 23:20:54
	System	10 Dec 2020 23:20:54

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-17T13:16:18', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '621b8923-93c1-44c9-ad92-631bac614745'	System	17 Dec 2020 19:16:33
User entered 'No (N)'	System	17 Dec 2020 19:16:33

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-17T13:16:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '621b8923-93c1-44c9-ad92-631bac614745'	System	17 Dec 2020 19:16:33
User entered 'No (N)'	System	17 Dec 2020 19:16:33

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-17T13:16:29', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '621b8923-93c1-44c9-ad92-631bac614745' User entered '17 Dec 2020 13:16:29'	System	17 Dec 2020 19:16:33
	System	17 Dec 2020 19:16:33

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-21T09:46:32', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9f8af4d-2470-4ea6-a785-dca6ef967e80' User entered 'No (N)'	System	21 Dec 2020 15:46:51
	System	21 Dec 2020 15:46:51

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-21T09:46:38', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9f8af4d-2470-4ea6-a785-dca6ef967e80' User entered 'No (N)'	System	21 Dec 2020 15:46:51
	System	21 Dec 2020 15:46:51

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-21T09:46:46', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'c9f8af4d-2470-4ea6-a785-dca6ef967e80' User entered '21 Dec 2020 09:46:46'	System	21 Dec 2020 15:46:51
	System	21 Dec 2020 15:46:51

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-28T07:19:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '534737de-5507-4512-8516-47d6542bec9d'	System	28 Dec 2020 13:20:17
User entered 'No (N)'	System	28 Dec 2020 13:20:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-28T07:19:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '534737de-5507-4512-8516-47d6542bec9d' User entered 'No (N)'	System	28 Dec 2020 13:20:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2020-12-28T07:20:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '534737de-5507-4512-8516-47d6542bec9d' User entered '28 Dec 2020 07:20:15'	System	28 Dec 2020 13:20:17
	System	28 Dec 2020 13:20:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-04T17:48:54', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5754592e-e06a-484b-9bec-a8805d1996af' User entered 'No (N)'	System	04 Jan 2021 23:49:12
	System	04 Jan 2021 23:49:12

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-04T17:48:57', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5754592e-e06a-484b-9bec-a8805d1996af' User entered 'No (N)'	System	04 Jan 2021 23:49:12

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-04T17:49:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5754592e-e06a-484b-9bec-a8805d1996af' User entered '04 Jan 2021 17:49:07'	System	04 Jan 2021 23:49:12
	System	04 Jan 2021 23:49:12

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-12T06:13:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5312f70c-3631-4f31-8138-9ce9b5698c1a' User entered 'No (N)'	System	12 Jan 2021 12:13:22
	System	12 Jan 2021 12:13:22

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-12T06:13:15', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5312f70c-3631-4f31-8138-9ce9b5698c1a' User entered 'No (N)'	System	12 Jan 2021 12:13:22

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-12T06:13:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '5312f70c-3631-4f31-8138-9ce9b5698c1a' User entered '12 Jan 2021 06:13:19'	System	12 Jan 2021 12:13:22
	System	12 Jan 2021 12:13:22

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-19T09:32:17', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f8d8780e-933b-4454-995e-7e3c74f3c6a1'	System	19 Jan 2021 15:32:29
User entered 'No (N)'	System	19 Jan 2021 15:32:29

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-19T09:32:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f8d8780e-933b-4454-995e-7e3c74f3c6a1' User entered 'No (N)'	System	19 Jan 2021 15:32:29

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-19T09:32:27', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f8d8780e-933b-4454-995e-7e3c74f3c6a1' User entered '19 Jan 2021 09:32:27'	System	19 Jan 2021 15:32:29
	System	19 Jan 2021 15:32:29

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-25T12:49:02', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f4389324-5e44-480d-9b09-eabce640eb98'	System	25 Jan 2021 18:49:19
User entered 'No (N)'	System	25 Jan 2021 18:49:19

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-25T12:49:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f4389324-5e44-480d-9b09-eabce640eb98'	System	25 Jan 2021 18:49:19
User entered 'No (N)'	System	25 Jan 2021 18:49:19

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-01-25T12:49:16', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f4389324-5e44-480d-9b09-eabce640eb98' User entered '25 Jan 2021 12:49:16'	System	25 Jan 2021 18:49:19
	System	25 Jan 2021 18:49:19

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-01T06:07:19', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f70d853a-20d8-4804-9887-baf09760c8ac'	System	02 Feb 2021 11:43:17
User entered 'Yes (Y)'	System	02 Feb 2021 11:43:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-01T06:07:26', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f70d853a-20d8-4804-9887-baf09760c8ac'	System	02 Feb 2021 11:43:17
User entered 'No (N)'	System	02 Feb 2021 11:43:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-01T06:07:32', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f70d853a-20d8-4804-9887-baf09760c8ac'	System	02 Feb 2021 11:43:17
User entered 'No (N)'	System	02 Feb 2021 11:43:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-01T06:07:39', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f70d853a-20d8-4804-9887-baf09760c8ac'	System	02 Feb 2021 11:43:17
User entered 'Yes (Y)'	System	02 Feb 2021 11:43:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Please 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-01T06:07:48', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f70d853a-20d8-4804-9887-baf09760c8ac'	System	02 Feb 2021 11:43:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Feb 2021 11:43:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-01T06:07:55', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f70d853a-20d8-4804-9887-baf09760c8ac' User entered '01 Feb 2021 06:07:55'	System	02 Feb 2021 11:43:17
	System	02 Feb 2021 11:43:17

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-08T07:19:33', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '6ed203e3-4f93-4b00-aa15-426ef8e5583e' User entered 'No (N)'	System	08 Feb 2021 13:19:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-08T07:19:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '6ed203e3-4f93-4b00-aa15-426ef8e5583e' User entered 'No (N)'	System	08 Feb 2021 13:19:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-08T07:19:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '6ed203e3-4f93-4b00-aa15-426ef8e5583e' User entered '08 Feb 2021 07:19:40'	System	08 Feb 2021 13:19:43
	System	08 Feb 2021 13:19:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-15T06:51:51', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7491d811-97cf-47fa-b117-92b6ca719a01'	System	15 Feb 2021 12:52:01
User entered 'No (N)'	System	15 Feb 2021 12:52:01

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-15T06:51:54', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7491d811-97cf-47fa-b117-92b6ca719a01'	System	15 Feb 2021 12:52:01
User entered 'No (N)'	System	15 Feb 2021 12:52:01

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-15T06:51:57', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7491d811-97cf-47fa-b117-92b6ca719a01' User entered '15 Feb 2021 06:51:57'	System	15 Feb 2021 12:52:01
	System	15 Feb 2021 12:52:01

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-21T10:02:42', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e803e178-89fb-45a1-bbc7-8556d853a7db' User entered 'No (N)'	System	21 Feb 2021 16:02:52
	System	21 Feb 2021 16:02:52

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-21T10:02:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e803e178-89fb-45a1-bbc7-8556d853a7db' User entered 'No (N)'	System	21 Feb 2021 16:02:52
	System	21 Feb 2021 16:02:52

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-21T10:02:49', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'e803e178-89fb-45a1-bbc7-8556d853a7db' User entered '21 Feb 2021 10:02:49'	System	21 Feb 2021 16:02:52
	System	21 Feb 2021 16:02:52

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-28T07:19:22', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f3701897-d221-4985-822c-30fddda4651f' User entered 'No (N)'	System	28 Feb 2021 13:19:36

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-28T07:19:25', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f3701897-d221-4985-822c-30fddda4651f' User entered 'No (N)'	System	28 Feb 2021 13:19:36

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-28T07:19:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'f3701897-d221-4985-822c-30fddda4651f' User entered '28 Feb 2021 07:19:30'	System	28 Feb 2021 13:19:36
	System	28 Feb 2021 13:19:36

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-07T13:57:31', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '318abcde-3091-445f-99da-9a68fbdea372'	System	07 Mar 2021 19:57:43
User entered 'No (N)'	System	07 Mar 2021 19:57:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-07T13:57:36', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '318abcde-3091-445f-99da-9a68fbdea372'	System	07 Mar 2021 19:57:43
User entered 'No (N)'	System	07 Mar 2021 19:57:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-07T13:57:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '318abcde-3091-445f-99da-9a68fbdea372' User entered '07 Mar 2021 13:57:41'	System	07 Mar 2021 19:57:43
	System	07 Mar 2021 19:57:43

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-14T07:08:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab40f1d-27e9-4156-82a7-8aad71281630'	System	14 Mar 2021 12:08:15
User entered 'No (N)'	System	14 Mar 2021 12:08:15

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-14T07:08:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab40f1d-27e9-4156-82a7-8aad71281630'	System	14 Mar 2021 12:08:15
User entered 'No (N)'	System	14 Mar 2021 12:08:15

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-14T07:08:12', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'fab40f1d-27e9-4156-82a7-8aad71281630' User entered '14 Mar 2021 07:08:12'	System	14 Mar 2021 12:08:15
	System	14 Mar 2021 12:08:15

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-21T18:01:37', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '512ca754-3581-4dd2-bc5c-0110edb088ed' User entered 'No (N)'	System	21 Mar 2021 23:03:53
	System	21 Mar 2021 23:03:53

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-21T18:01:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '512ca754-3581-4dd2-bc5c-0110edb088ed' User entered 'No (N)'	System	21 Mar 2021 23:03:53

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-21T18:01:45', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '512ca754-3581-4dd2-bc5c-0110edb088ed' User entered '21 Mar 2021 18:01:45'	System	21 Mar 2021 23:03:53
	System	21 Mar 2021 23:03:53

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-29T06:58:40', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7137ac1f-582b-4d5a-951b-14bdc6c54d4c'	System	29 Mar 2021 11:58:52
User entered 'No (N)'	System	29 Mar 2021 11:58:52

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-29T06:58:44', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7137ac1f-582b-4d5a-951b-14bdc6c54d4c' User entered 'No (N)'	System	29 Mar 2021 11:58:52

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-03-29T06:58:50', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '7137ac1f-582b-4d5a-951b-14bdc6c54d4c' User entered '29 Mar 2021 06:58:50'	System	29 Mar 2021 11:58:52
	System	29 Mar 2021 11:58:52

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-04T08:35:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4bac3107-482e-4ca4-bb2e-f0b49e25fb14' User entered 'No (N)'	System	04 Apr 2021 13:36:12
	System	04 Apr 2021 13:36:12

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-04T08:36:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4bac3107-482e-4ca4-bb2e-f0b49e25fb14'	System	04 Apr 2021 13:36:12
User entered 'No (N)'	System	04 Apr 2021 13:36:12

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-04T08:36:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '4bac3107-482e-4ca4-bb2e-f0b49e25fb14'	System	04 Apr 2021 13:36:12
User entered '04 Apr 2021 08:36:07'	System	04 Apr 2021 13:36:12

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-12T06:09:59', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de509f8-5cae-4cfe-8d29-a47250452fd1' User entered 'No (N)'	System	12 Apr 2021 11:10:13
	System	12 Apr 2021 11:10:13

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-12T06:09:43', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de509f8-5cae-4cfe-8d29-a47250452fd1' User entered 'No (N)'	System	12 Apr 2021 11:10:13

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-12T06:10:09', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '8de509f8-5cae-4cfe-8d29-a47250452fd1' User entered '12 Apr 2021 06:10:09'	System	12 Apr 2021 11:10:13
	System	12 Apr 2021 11:10:13

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-18T09:12:05', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'bf58e0ad-c375-4136-bc2e-35d7df017da2'	System	18 Apr 2021 14:12:14
User entered 'No (N)'	System	18 Apr 2021 14:12:14

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-18T09:12:07', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'bf58e0ad-c375-4136-bc2e-35d7df017da2'	System	18 Apr 2021 14:12:14
User entered 'No (N)'	System	18 Apr 2021 14:12:14

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-18T09:12:11', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: 'bf58e0ad-c375-4136-bc2e-35d7df017da2'	System	18 Apr 2021 14:12:14
User entered '18 Apr 2021 09:12:11'	System	18 Apr 2021 14:12:14

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-25T16:09:58', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '66f1e371-97c5-4275-a2cf-5011117fcb57'	System	25 Apr 2021 21:10:08
User entered 'No (N)'	System	25 Apr 2021 21:10:08

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-25T16:10:01', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '66f1e371-97c5-4275-a2cf-5011117fcb57'	System	25 Apr 2021 21:10:08
User entered 'No (N)'	System	25 Apr 2021 21:10:08

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-04-25T16:10:04', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '66f1e371-97c5-4275-a2cf-5011117fcb57'	System	25 Apr 2021 21:10:08
User entered '25 Apr 2021 16:10:04'	System	25 Apr 2021 21:10:08

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-05-02T08:06:24', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '25def218-5f82-40d6-8fe6-3e61c863fa12'	System	02 May 2021 13:06:35
User entered 'No (N)'	System	02 May 2021 13:06:35

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

Have you been exposed to someone with 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 (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-05-02T08:06:26', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '25def218-5f82-40d6-8fe6-3e61c863fa12'	System	02 May 2021 13:06:35
User entered 'No (N)'	System	02 May 2021 13:06:35

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-05-02T08:06:30', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '25def218-5f82-40d6-8fe6-3e61c863fa12'	System	02 May 2021 13:06:35
User entered '02 May 2021 08:06:30'	System	02 May 2021 13:06:35

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:34:45

US3232162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:09:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:45
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:34:45

US3232162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:09:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-28T07:19:37', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0b0e60ba-a87c-4044-beb3-232322ba9178'	(b) (4), (b) (6)	28 Feb 2021 13:19:43
User entered 'No (N)'	System	28 Feb 2021 13:19:43

US3232162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:09:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0A06E915-7084-4261-8010-BD76ABDC079C)', Time: '2021-02-28T07:19:41', User OID: 'PatientReportedOutcome (US3232162)', ODM File OID: '0b0e60ba-a87c-4044-beb3-232322ba9178' User entered '28 Feb 2021 07:19:41'	(b) (4), (b) (6) System	28 Feb 2021 13:19:43
	System	28 Feb 2021 13:19:43

US3232162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:52:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	07 Dec 2020 13:43:45
	(b) (4)	

US3232162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:52:00
	(b) (4)	
User entered '04 Dec 2020'	Jerrica Sullivan (b) (4)	07 Dec 2020 13:43:45
	(b) (4)	

US3232162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:52:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	07 Dec 2020 13:43:45
	(b) (4)	

US3232162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:52:00
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	07 Dec 2020 13:43:45
	(b) (4)	

US3232162

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	05 Mar 2021 16:52:00
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	07 Dec 2020 13:43:51
	(b) (4)	

US3232162

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:18
User entered 'I'	System	07 Dec 2020 13:43:51

US3232162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:37
	(b) (4)	

US3232162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:37
	(b) (4)	

US3232162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:37
	(b) (4)	

US3232162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:37
	(b) (4)	

US3232162

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:41
	(b) (4)	

US3232162

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
User entered 'I'	(b) (4), (b) (6) System	05 Feb 2021 20:51:41

US3232162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:56
	(b) (4)	

US3232162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '05 Feb 2021'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:56
	(b) (4)	

US3232162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:56
	(b) (4)	

US3232162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	05 Feb 2021 20:51:56
	(b) (4)	

US3232162

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	05 Feb 2021 20:52:04
	(b) (4)	

US3232162

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
User entered 'I'	(b) (4), (b) (6) System	05 Feb 2021 20:52:04

US3232162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Mar 2021 15:48:36
	(b) (4)	

US3232162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '08 Mar 2021'	Jerrica Sullivan (b) (4)	08 Mar 2021 15:48:36
	(b) (4)	

US3232162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jerrica Sullivan (b) (4)	08 Mar 2021 15:48:36
	(b) (4)	

US3232162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:09:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Mar 2021 15:48:36
	(b) (4)	

US3232162

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Mar 2021 15:49:25
	(b) (4)	

US3232162

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:35:02
User entered 'I'	(b) (4), (b) (6) System	08 Mar 2021 15:49:25

US3232162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:15

US3232162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered '9 Apr 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:15

US3232162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered 'Clinic (Clinic)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:15

US3232162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered 'VISIT4'	(b) (4), (b) (6) System	09 Apr 2021 14:35:15

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4)	09 Apr 2021 14:35:22
	(b) (4)	

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4)	09 Apr 2021 14:35:22
	(b) (4)	

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered empty.	(b) (4) Adreanna Pou (b) (4)	09 Apr 2021 14:35:22
	(b) (4)	

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered empty.	(b) (4), (b) (6) System	09 Apr 2021 14:35:22

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 22:14:56

US3232162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:09:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 22:14:56

US3232162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:29

US3232162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:09:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered '9 Apr 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:29

US3232162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:41

US3232162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered '9 Apr 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:41

US3232162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered '08:54'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:41

US3232162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered '9 Apr 2021 08:54'	(b) (4), (b) (6) System	09 Apr 2021 14:35:41

US3232162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Apr 2021 14:35:47

US3232162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:09:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:56
User entered 'I'	(b) (4), (b) (6) System	09 Apr 2021 14:35:47

US3232162

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

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	15 Jan 2021 19:30:53
	(b) (4)	

US3232162

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

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '15 Jan 2021'	Adreanna Pou (b) (4)	15 Jan 2021 19:30:53
	(b) (4)	

US3232162

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

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Clinic (Clinic)'	Adreanna Pou (b) (4)	15 Jan 2021 19:30:53
	(b) (4)	

US3232162

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

Form: Visit Date

Generated On: 09 Jun 2021 16:09:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:20:42
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	15 Jan 2021 19:30:53

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '15 Jan 2021'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:06
	(b) (4)	

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered '0'	(b) (4) Jerrica Sullivan (b) (4)	09 Mar 2021 14:56:19
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:59:50

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:06
	(b) (4)	

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Jerrica Sullivan (b) (4)	09 Mar 2021 14:56:19
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:59:50

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '15 Jan 2021'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:06
	(b) (4)	

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 19:31:06

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 09:22:52
User entered 'mRNA-1273 (mRNA-1273)'	Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 19:31:06

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 09:22:52
User entered 'mRNA-1273 (mRNA-1273)'	Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 19:31:06

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:06
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User entered empty.	(b) (4), (b) (6) System	15 Jan 2021 19:31:06

US3232162

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

Form: Unblinding

Generated On: 09 Jun 2021 16:09:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User entered empty.	(b) (4), (b) (6) System	15 Jan 2021 19:31:06

US3232162

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:21
	(b) (4)	

US3232162

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '15 Jan 2021'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:21
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '12:30'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:21
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User entered '15 Jan 2021 12:30'	(b) (4), (b) (6) System	15 Jan 2021 19:31:21

US3232162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 19:31:58

US3232162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered '15 Jan 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	15 Jan 2021 19:31:58

US3232162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '12:24'	Adreanna Pou (b) (4)	15 Jan 2021 19:31:58
	(b) (4)	

US3232162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:58
User entered '15 Jan 2021 12:24'	(b) (4), (b) (6) System	15 Jan 2021 19:31:58

US3232162

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:09:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:55
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:25:58
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:05
User entered 'USA-US105-2021-mRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02
User entered 'New'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 17:04:02

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive cardiac failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 23:36:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 23:36:48
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 14:00:25
Coding entries removed.	Jerrica Sullivan (b) (4)	24 Mar 2021 13:59:59
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	24 Mar 2021 13:59:59
	(b) (4)	
User entered 'acute exacerbation of congestive heart failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 13:59:59
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:56:17
	(b) (4), (b) (6)	
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 18:58:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 18:58:00
	(b) (4)	
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:59
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 18:57:34
Coding entries removed.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:56:51
	(b) (4)	
User entered 'new onset Congestive Heart Failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:56:51
	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:19:13
	(b) (4), (b) (6)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 16:43:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Feb 2021 16:43:34
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 16:27:52
User entered 'shortness of breath'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:01:13
	(b) (4)	
User entered '29 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:01:13
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '31 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	26 Feb 2021 17:44:03
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 16:26:59

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '02 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:56:51
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 16:26:59

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	17 Feb 2021 13:26:24
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:56:51
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:14:30
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:13:41
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:13:41
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	09 Feb 2021 14:58:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Feb 2021 14:58:32
	(b) (4)	
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	09 Feb 2021 14:58:17
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	25 Feb 2021 18:56:51
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 18:56:51
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:56:51
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	25 Feb 2021 18:14:30
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Feb 2021 18:14:30
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	25 Feb 2021 18:14:30
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:14:30
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Feb 2021 18:14:17
User closed query 'PV Query: Since the subject was hospitalized for the event of shortness of breath, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 14:54:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Query 'PV Query: Since the subject was hospitalized for the event of shortness of breath, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4)	17 Feb 2021 13:25:38
User opened query 'PV Query: Since the subject was hospitalized for the event of shortness of breath, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 18:17:09
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 14:59:05
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		09 Feb 2021 14:59:05
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		09 Feb 2021 14:58:17
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		09 Feb 2021 14:58:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Feb 2021 14:58:17
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Feb 2021 14:58:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	09 Feb 2021 14:58:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:26:59

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User closed query 'PV Query: Please clarify hospital admission date of 29 Jan 2021 as discharge summary reports the subject was evaluated on 31 Jan 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 14:55:04
Query 'PV Query: Please clarify hospital admission date of 29 Jan 2021 as discharge summary reports the subject was evaluated on 31 Jan 2021.' answered with 'updated as patient was transferred to another hospital for admission. new records sent ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 17:27:18
User opened query 'PV Query: Please clarify hospital admission date of 29 Jan 2021 as discharge summary reports the subject was evaluated on 31 Jan 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 14:37:59
User entered '31 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:56:51
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:14:17
User entered '29 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Feb 2021 14:58:10
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:26:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User closed query 'PV Query: Per discharge summary, the subject was transferred from one hospital to another hospital for admission with cardiology to consult. Please send a hospital discharge summary and any relevant laboratory and diagnostic test results (for the second hospital the subject was admitted to included cardiology consult noted)with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 14:55:15
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 14:55:08
Query 'PV Query: Per discharge summary, the subject was transferred from one hospital to another hospital for admission with cardiology to consult. Please send a hospital discharge summary and any relevant laboratory and diagnostic test results (for the second hospital the subject was admitted to included cardiology consult noted)with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records sent this date 26feb2021' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 17:28:27

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'hospital transfer records sent ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 17:27:41
User opened query 'PV Query: Per discharge summary, the subject was transferred from one hospital to another hospital for admission with cardiology to consult. Please send a hospital discharge summary and any relevant laboratory and diagnostic test results (for the second hospital the subject was admitted to included cardiology consult noted)with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 14:38:24
User entered '02 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:56:51
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:14:17
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Feb 2021 18:19:57
User entered '31 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Feb 2021 14:58:10
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:26:59

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Feb 2021 14:59:05
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 14:58:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 14:58:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Feb 2021 14:58:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:26:59
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 14:58:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 14:58:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Feb 2021 14:58:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:26:59
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User closed query 'PV Query: As the last dose of study drug was given on 09 Oct 2020, please consider updating the action taken with study drug from none to not applicable and please update the EDC accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 17:03:03
Query 'PV Query: As the last dose of study drug was given on 09 Oct 2020, please consider updating the action taken with study drug from none to not applicable and please update the EDC accordingly.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	04 Mar 2021 16:02:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	04 Mar 2021 16:01:43
User opened query 'PV Query: As the last dose of study drug was given on 09 Oct 2020, please consider updating the action taken with study drug from none to not applicable and please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 13:55:01
User entered 'None (NONE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:58:17
User closed query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 14:54:16
Query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	17 Feb 2021 13:26:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	17 Feb 2021 13:26:24
User opened query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Feb 2021 18:15:43
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:26:59

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:01:22
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User closed query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly, else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 11:09:42
Query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly, else clarify' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:58:28
User opened query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly, else clarify' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Feb 2021 17:56:09
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:26:59

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
Signature has been broken.	Jerrica Sullivan (b) (4)	24 Mar 2021 13:52:48
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 13:52:48
	(b) (4)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:26:59
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject had CTA Chest and Echocardiogram. However, there are no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Mar 2021 09:01:55
Query 'Per DM CLR: Narrative indicates that the subject had CTA Chest and Echocardiogram. However, there are no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 13:52:36
User opened query 'Per DM CLR: Narrative indicates that the subject had CTA Chest and Echocardiogram. However, there are no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Mar 2021 11:29:57
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User closed query 'PV Query: As per the discharge summary, the subject does not have a diagnosis of hypertension, however he self medicated with losartan in the past for renal protection due to his diabetes. Please consider updating the medical history and eCRF accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 17:03:06
Query 'PV Query: As per the discharge summary, the subject does not have a diagnosis of hypertension, however he self medicated with losartan in the past for renal protection due to his diabetes. Please consider updating the medical history and eCRF accordingly.' answered with 'hypertension is on medical history list in screening visit, updated med list' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	04 Mar 2021 16:43:33
User opened query 'PV Query: As per the discharge summary, the subject does not have a diagnosis of hypertension, however he self medicated with losartan in the past for renal protection due to his diabetes. Please consider updating the medical history and eCRF accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 13:56:05

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[Narrative](#)

Audit	User	Time (GMT)
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) (b) (4), (b) (6)	01 Mar 2021 14:55:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 14:55:19
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 'updated in summary ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 17:27:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'sent' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 17:27:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 17:26:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 17:26:49

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient presented to the ER on 31Jan2021 C/O worsening SOB/DOE x 2 days and palpitations. He was diagnosed with new onset idiopathic dilated cardiomyopathy with acute combined systolic and diastolic CHF; a newly diagnosed RBBB was also noted. Subject was admitted to the hospital and underwent further evaluation with CTA chest which was negative for PE. Echocardiogram revealed severe global hypokinesis and moderate dilation of LV chamber. Symptoms improved after diuresis with Lasix. Patient started on Entresto, Coreg and spironolactone. Cardiology was consulted and recommended an outpatient ischemic evaluation. Patient was discharged from the hospital on 02Feb2021 with a cardiologist follow-up appointment.' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	26 Feb 2021 17:26:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 16:56:24
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) (b) (4), (b) (6)	26 Feb 2021 14:36:17
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'result sent ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:58:37
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 18:56:51
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 18:13:41

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[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 18:13:41
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) (b) (4), (b) (6)	18 Feb 2021 14:54:21
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 'awaiting medical records to confirm treatments ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	17 Feb 2021 13:27:09
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) (b) (4), (b) (6)	16 Feb 2021 18:18:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Feb 2021 18:17:42
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Feb 2021 18:16:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Feb 2021 14:58:32
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:26:59

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 18:56:51
User entered '0'	System	25 Feb 2021 18:13:41
User entered '1'	System	09 Feb 2021 14:58:32
User entered '0'	System	08 Feb 2021 16:26:59

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Feb 2021 16:26:59

US3232162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:09:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 14:59:05

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Bundle branch block right, LLT: Right bundle branch block - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 06:01:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 06:01:09
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 18:58:34
User entered 'new onset right bundle branch block'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
User entered empty.	(b) (4), (b) (6) System	25 Feb 2021 18:57:49

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '25 Feb 2021'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
User entered empty.	(b) (4), (b) (6) System	25 Feb 2021 18:57:49

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:28:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 17:28:07
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	26 Feb 2021 17:28:07
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 18:57:49
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:28:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 17:28:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	26 Feb 2021 17:28:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 18:57:49
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'None (NONE)'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'I'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:57:49

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[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 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 18:57:49
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
User entered '0'	(b) (4), (b) (6) System	25 Feb 2021 18:57:49

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
User entered '1'	(b) (4), (b) (6) System	25 Feb 2021 18:57:49

US3232162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:09:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:42:06
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 18:09:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 18:09:49
	(b) (4)	
Data point term sent to Coder	System	03 Mar 2021 18:08:30
User entered 'worsening of diabetes type II'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:07:42

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:07:42

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Mar 2021 21:09:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Mar 2021 21:09:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Adreanna Pou (b) (4)	11 Mar 2021 21:09:36
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 18:07:42
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:33
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	03 Mar 2021 18:07:42
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 18:07:42

US3232162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:09:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 18:07:42

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Essential hypertension, LLT: Essential hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:27:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:27:19
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	26 Mar 2021 14:20:41
Data point term sent to Coder	System	24 Mar 2021 14:21:59
User entered 'worsened chronic essential hypertension'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:21:36

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:21:36

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[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) (b) (4), (b) (6)	06 Apr 2021 14:05:33
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 'this is still ongoing ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 13:35:43
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) (b) (4), (b) (6)	03 Apr 2021 06:06:31
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	26 Mar 2021 14:20:41
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:21:36

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 14:21:36

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 14:41:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:41:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:21:36
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:41:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 14:41:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:41:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:21:36
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

None

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '1'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:21:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 14:21:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:42
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 14:21:36
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	26 Mar 2021 14:20:41
	(b) (4)	
User entered 'started coreg 12.5mg 31Jan2021 and was increased to 25mg BID on 25Feb2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:22:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:21:36
	(b) (4)	

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 14:21:36

US3232162

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:09:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 14:21:36

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:55
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	28 Sep 2020 18:32:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:34:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 18:34:38
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 18:33:31
User entered 'metformin'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'type 2 diabetes'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '500'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered 'mg (mg)'	(b) (4) Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'un UNK 2015'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Feb 2021 16:30:04
	(b) (4)	
User entered 'Yes (Y)'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Feb 2021 16:30:04
	(b) (4)	
User entered empty.	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Adreanna Pou (b) (4)	28 Sep 2020 18:33:20
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User entered '2'	(b) (4), (b) (6) System	28 Sep 2020 18:33:20

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User entered '1'	(b) (4), (b) (6) System	28 Sep 2020 18:33:20

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:58
User entered '804 (804)'	(b) (4), (b) (6) System	28 Sep 2020 18:33:20

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 31 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 11:11:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, PRODUCTSYNONYM: FARXIGA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 18:06:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 18:06:42
Data point term sent to Coder	System	03 Mar 2021 18:05:26
Query 'Per DM CLR: this Con Med was added/ had dose increased on 31 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'ae log updated ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	03 Mar 2021 18:05:10
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	03 Mar 2021 18:05:01
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 31 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 00:35:26

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, PRODUCTSYNONYM: FARXIGA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 16:28:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 16:28:34
Data point term sent to Coder	System	08 Feb 2021 16:27:52
User entered 'farxiga'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'worsening of DIABETES' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	03 Mar 2021 18:05:01
	(b) (4)	
User entered 'diabetes'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '5'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 15:50:20
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '08 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Mar 2021 15:50:20
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:27:38
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 16:27:38

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 16:27:38

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:04
User entered '804 (804)'	(b) (4), (b) (6) System	08 Feb 2021 16:27:38

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: OTHER VASODILATORS USED IN CARDIAC DISEASES, PRODUCT: SACUBITRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:53:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:53:51
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 14:14:37
Data point term sent to Coder	System	24 Mar 2021 14:12:36
Coding entries removed.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:12:13
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: OTHER VASODILATORS USED IN CARDIAC DISEASES, PRODUCT: SACUBITRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 12:02:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 12:02:45
	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 16:28:55
User entered 'sacubitril'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'acute exacerbation of CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:13:54
	(b) (4)	
User entered 'congestive heart failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:12:13
	(b) (4)	
User entered 'hypertension'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '24'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:05:36
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (02 FEB 2021). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:00:14
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (02 FEB 2021). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'confirm correct as entered' (Site from DM).	Jerrica Sullivan (b) (4)	07 Apr 2021 12:58:52
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (02 FEB 2021). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:14:27
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:17:32
User entered '14 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:05:36
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:05
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User entered '2'	(b) (4), (b) (6) System	08 Feb 2021 16:28:05

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 16:28:05

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:10
User entered '804 (804)'	(b) (4), (b) (6) System	08 Feb 2021 16:28:05

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 08:30:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:30:50
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:37 24 Mar 2021 14:14:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 14:13:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:13:34
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	24 Mar 2021 14:12:36 24 Mar 2021 14:11:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Feb 2021 16:45:33

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Feb 2021 16:45:33
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Feb 2021 16:28:55
User entered 'valsartan'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'acute exacerbation of CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:05
	(b) (4)	
User entered 'congestive heart failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:57
	(b) (4)	
User entered 'hypertension'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
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) (6)	12 Apr 2021 16:00:43
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 'confirm correct as entered' (Site from DM).	Jerrica Sullivan (b) (4)	07 Apr 2021 16:07:16
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)	07 Apr 2021 10:14:45
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered '26'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:57
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (02 FEB 2021). Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:01:06
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (02 FEB 2021). Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'patient continued to take doseage until follow up with MD' (Site from DM).	Jerrica Sullivan (b) (4)	07 Apr 2021 16:08:49
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE (02 FEB 2021). Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:15:02
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:17:32
User entered '14 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:57
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:30
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User entered '2'	(b) (4), (b) (6) System	08 Feb 2021 16:28:30

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 16:28:30

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:15
User entered '804 (804)'	(b) (4), (b) (6) System	08 Feb 2021 16:28:30

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:13:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Mar 2021 14:04:34
Data point term sent to Coder	(b) (4)	
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification.	Coder Import (b) (4)	24 Mar 2021 14:04:34
' answered with 'updated' (Site from DM).	System	24 Mar 2021 14:03:27
Coding entries removed.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:03:03
	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:02:58
' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	21 Mar 2021 09:33:28
	(b) (4), (b) (6)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 16:30:34
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 Feb 2021 16:30:34
Data point term sent to Coder	System	08 Feb 2021 16:29:55
User entered 'coreg'	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:28:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'worsened HYPERTENSION' reason	Jerrica Sullivan (b) (4)	24 Mar 2021 14:02:58
for change: Data Entry Error	(b) (4)	
User entered 'hypertension'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
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.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:12:10
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.	(b) (4), (b) (6)	
' answered with 'updated dose ' (Site from DM).	Jerrica Sullivan (b) (4)	03 Mar 2021 18:15:06
User entered '12.5' reason for change: Data Entry Error	(b) (4)	
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.	(b) (4), (b) (6)	03 Mar 2021 18:14:46
' (Site from DM).	(b) (4), (b) (6)	
User entered '2.5'	Jerrica Sullivan (b) (4)	03 Mar 2021 00:37:16
	(b) (4)	
	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:18:42
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '24 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:18:42
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:28:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User entered '2'	(b) (4), (b) (6) System	08 Feb 2021 16:28:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 16:28:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:22
User entered '804 (804)'	(b) (4), (b) (6) System	08 Feb 2021 16:28:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 11:58:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:58:10
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:18:43 24 Mar 2021 14:17:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:01:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:01:00
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:59:35 25 Feb 2021 18:59:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 16:45:34
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 Feb 2021 16:45:34
Data point term sent to Coder User entered 'spironolactone'	System Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:29:55 08 Feb 2021 16:29:18

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'acute exacerbation of CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:17:43
	(b) (4)	
User entered 'Congestive heart failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:59:17
	(b) (4)	
User entered 'edema'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '25'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Feb 2021 16:29:27
User entered '31 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:27
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Feb 2021 16:29:18
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 10:30:08
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'patient is continuing to take medications ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 15:50:04
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 07:36:01
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:29:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 16:29:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:29:27
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:29:18
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:29:18

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:29:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 16:29:27
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 16:29:18
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:18
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 16:29:18

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 16:29:18

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Feb 2021 16:29:18

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 12:16:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:16:26
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:18:43 24 Mar 2021 14:17:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:00:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 19:00:59
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 18:59:35 25 Feb 2021 18:59:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 16:30:34
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 Feb 2021 16:30:34
Data point term sent to Coder User entered 'Lasix'	System Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:29:55 08 Feb 2021 16:29:47

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'acute exacerbation of CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:17:56
	(b) (4)	
User entered 'congestive heart failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Feb 2021 18:59:31
	(b) (4)	
User entered 'edema'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '40'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 10:30:13
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'patient is continuing to take medications ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	11 Mar 2021 15:50:19
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Mar 2021 07:36:08
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	08 Feb 2021 16:29:47

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Feb 2021 16:29:47
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 16:29:47

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 16:29:47

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 16:29:47

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	25 Mar 2021 12:25:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	25 Mar 2021 12:25:27
Data point term sent to Coders	System	24 Mar 2021 14:17:42
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:16:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	25 Feb 2021 19:01:01
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	25 Feb 2021 19:01:01
Data point term sent to Coders	System	25 Feb 2021 19:00:36
User entered 'furosemide'	Jerrica Sullivan (b) (4) (b) (4)	25 Feb 2021 19:00:13

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'acute exacerbation of CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:16:46
	(b) (4)	
User entered 'congestive heart failure'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '20'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Feb 2021 19:00:13
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User entered '1'	(b) (4), (b) (6) System	25 Feb 2021 19:00:13

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User entered '1'	(b) (4), (b) (6) System	25 Feb 2021 19:00:13

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:37
User entered '804 (804)'	(b) (4), (b) (6) System	25 Feb 2021 19:00:13

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 22:54:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 22:54:54
	(b) (4)	
Data point term sent to Coder	System	04 Mar 2021 16:46:28
User entered 'losartan'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'prophylactic renal protection'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '50'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'once daily (QD)'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'un Nov 2019'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '29 Jan 2021'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User signature succeeded.	(b) (4), (b) (6)	
	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	04 Mar 2021 16:46:27
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User entered '1'	(b) (4), (b) (6) System	04 Mar 2021 16:46:27

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User entered '1'	(b) (4), (b) (6) System	04 Mar 2021 16:46:27

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:24:41
User entered '804 (804)'	(b) (4), (b) (6) System	04 Mar 2021 16:46:27

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: OTHER VASODILATORS USED IN CARDIAC DISEASES, PRODUCT: SACUBITRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 08:56:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:56:50
Data point term sent to Coder	System	24 Mar 2021 14:14:39
Data point term sent to Coder	System	24 Mar 2021 14:11:35
User entered 'sacubitril'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:11:28

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'chronic CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:21
	(b) (4)	
User entered 'congestive heart failure'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '97' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:29
	(b) (4)	
User entered '97-103'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '15 Mar 2021'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:11:28
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:11:28

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 14:11:28

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 14:11:28

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 08:30:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:30:51
Data point term sent to Coder	System	24 Mar 2021 14:15:39
User entered 'valsartan'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:14:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'CHRONIC diastolic and systolic combined congestive heart failure' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 14:15:39
	(b) (4)	
User entered 'chronic congestive heart failure'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
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) (6) (b) (4), (b) (6)	15 Apr 2021 15:52:17
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 'confirm correct as entered' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	07 Apr 2021 16:10:08
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) (b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:16:01
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:17:32
User entered '103'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:14:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '15 Mar 2021'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:14:59
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:14:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 14:14:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 14:14:59

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:21:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:21:36
Data point term sent to Coder	System	24 Mar 2021 14:20:58
User entered 'coreg'	Jerrica Sullivan (b) (4) (b) (4)	24 Mar 2021 14:19:58

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'worsened chronic essential hypertension'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '25'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'twice daily (BID)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '25 Feb 2021'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

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

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	24 Mar 2021 14:19:58
	(b) (4)	

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Mar 2021 14:19:58

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 14:19:58

US3232162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:09:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 14:19:58

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:09:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:55
	(b) (4), (b) (6)	
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	24 Mar 2021 13:51:43
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Mar 2021 20:47:46
	(b) (4)	

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '31 Jan 2021'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:52:13
	(b) (4)	

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'CTA of Chest with Echocardiogram'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:52:13
	(b) (4)	

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered 'Adverse Event (AE)'	Jerrica Sullivan (b) (4)	24 Mar 2021 13:52:13
	(b) (4)	

US3232162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:09:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	24 Mar 2021 13:52:13
	(b) (4)	

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:09:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '10/Feb/2021 12:04'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:09:18

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.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:09:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '18/Feb/2021 09:55'	System	18 Feb 2021 14:55:07

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:09:18

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.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 14:55:07

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:09:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '26/Feb/2021 11:56'	System	26 Feb 2021 16:56:53

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:09:18

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.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:55:31
User entered 'I'	(b) (4), (b) (6)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:53
	(b) (4), (b) (6)	

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:09:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '01/Mar/2021 09:56'	System	01 Mar 2021 14:56:13

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:09:18

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.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 17:03:32
User entered 'I'	(b) (4), (b) (6)	
	(b) (4), (b) (6)	01 Mar 2021 14:56:13
	(b) (4), (b) (6)	

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:09:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered '05/Mar/2021 12:03'	(b) (4) System	05 Mar 2021 17:03:50

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:09:18

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.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:16:52
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 17:03:50

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'USA-US105-2021-MRNA-1273-P301000005'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

Serious

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 16:56:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	25 Feb 2021 18:56:51
Un-reviewed for Safety.	System	25 Feb 2021 18:14:30
User entered 'No (N)'	System	25 Feb 2021 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:04:19
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'No (N)'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rambod'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'Petal'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered 'MS'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:04:19
User entered '39465'	(b) (4), (b) (6) System	10 Feb 2021 17:04:02

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:55:15
User entered 'US'	(b) (4), (b) (6) System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:09:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	25 Mar 2021 15:17:03
User entered '5'	System	05 Mar 2021 17:03:50
User entered '4'	System	01 Mar 2021 14:56:13
User entered '3'	System	26 Feb 2021 16:56:53
User entered '2'	System	18 Feb 2021 14:55:07
User entered '1'	System	10 Feb 2021 17:04:30

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:09:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
	(b) (4)	
User entered '25/Mar/2021 10:16'	System	25 Mar 2021 15:17:03

US3232162

Folder: SAE USA-US105-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:09:18

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.	Rambod Rouhbakhsh	02 Apr 2021 14:17:32
User entered 'I'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Mar 2021 15:17:03