

US3242017 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:10:53

All time stamps listed in this document are displayed in GMT

US3242017

Form: Participant Creation

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Participant ID

US3242017

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

US3242017

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

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

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3242017

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	64
Age Units	YEARS
Age (Derived)	64
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

US3242017

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	7 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3242017

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3242017

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Were any significant conditions reported?

Yes ☒
No ☐

US3242017

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Condition	HYPERTENSION
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)	

US3242017

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Condition	BENIGN PROSTATIC HYPERPLASIA
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)	

US3242017

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242017

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:54 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 08:54
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	261 lb
BMI (<i>xxx.x</i>)	34.50680 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)	

US3242017

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

US3242017

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Sep 2020 12:58:08

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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

INTERACTS WITH PUBLIC
DAILY (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3242017

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Sep 2020 12:58:08

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

US3242017

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

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

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3242017

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143121

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 ☒

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Height	ND - Not Done
Weight	ND - Not Done

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

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)	07 AUG 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 08:54
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:30
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3242017

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

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.

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

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) 7 AUG 2020

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 10:49

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

US3242017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 AUG 2020
Collection time (00:00-23:59)	10:16 (24 HR)
Collection date and time (derived)	07 AUG 2020 10:16

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:08	07 AUG 2020 10:08
Nasopharyngeal Swab 2	No		

US3242017

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 12:58:07

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 11:32

PC Open Date & Time

07 AUG 2020 11:09

PC Close Date & Time

07 AUG 2020 13:39

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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 97.4 °F

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

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

PC Time Stamp	07 AUG 2020 22:43
PC Open Date & Time	07 AUG 2020 14:34
PC Close Date & Time	08 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 22:56

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

09 AUG 2020 20:57

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

11 AUG 2020 11:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:21

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

12 AUG 2020 22:18

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

13 AUG 2020 23:46

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

07 AUG 2020 11:32

PC Open Date & Time

07 AUG 2020 11:09

PC Close Date & Time

07 AUG 2020 13:39

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

07 AUG 2020 22:44

PC Open Date & Time

07 AUG 2020 14:34

PC Close Date & Time

08 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

08 AUG 2020 22:58

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

09 AUG 2020 20:58

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 11:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

11 AUG 2020 17:21

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

12 AUG 2020 22:18

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

13 AUG 2020 23:47

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 11:33
PC Open Date & Time	07 AUG 2020 11:09
PC Close Date & Time	07 AUG 2020 13:39

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 22:44
PC Open Date & Time	07 AUG 2020 14:34
PC Close Date & Time	08 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:58
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 11:42
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

50 of 2184

EAB) (1725)

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:21
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 22:18
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 23:47
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3242017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 12:58:07

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 12:58:07

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 12:58:07

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 08:25
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:57
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3242017

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

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.

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 8 SEP 2020

What was the treatment time? (00:00-23:59) 09:27 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 09:27

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

US3242017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 08 SEP 2020

Collection time (00:00-23:59) 08:50 (24 HR)

Collection date and time (derived) 08 SEP 2020 08:50

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:40	08 SEP 2020 08:40
Nasopharyngeal Swab 2	No		

US3242017

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 10 Sep 2020 12:58:07

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

08 SEP 2020 10:01

PC Open Date & Time

08 SEP 2020 09:47

PC Close Date & Time

08 SEP 2020 12:17

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

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

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

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

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

PC Time Stamp 09 SEP 2020 07:09

PC Open Date & Time 08 SEP 2020 13:12

PC Close Date & Time 09 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 06:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

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

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 09:14

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

13 SEP 2020 13:29

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 08:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 10:03

PC Open Date & Time

08 SEP 2020 09:47

PC Close Date & Time

08 SEP 2020 12:17

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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 SEP 2020 07:10

PC Open Date & Time

08 SEP 2020 13:12

PC Close Date & Time

09 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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 SEP 2020 06:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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 ☐

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.**

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

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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 SEP 2020 09:14

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 13:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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 SEP 2020 08:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 10:01
PC Open Date & Time	08 SEP 2020 09:47
PC Close Date & Time	08 SEP 2020 12:17

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 07:11
PC Open Date & Time	08 SEP 2020 13:12
PC Close Date & Time	09 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 06:39
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 09:15
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

96 of 2184

EAB) (1725)

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:01
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 2184

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:30
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

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 ☒

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 08:01
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3242017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	08:56 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 08:56
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

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.

US3242017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	08 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	09:45 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	08 OCT 2020 09:45
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US3242017

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 OCT 2020 08:57:12
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 17:52:36

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 13:49:08

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:52:14

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 16:18:36
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 23:33:03

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 12:22:11
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 14:37:48

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

30 NOV 2020 08:34:22

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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	07 DEC 2020 09:57:43
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 00:01:34
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

21 DEC 2020 10:21:40

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 14:55:52

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 <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	03 JAN 2021 00:01:29
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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	12 JAN 2021 15:22:41
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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	18 JAN 2021 23:29:36
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 12:30:42

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☒

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 FEB 2021 13:33:46

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

07 FEB 2021 00:01:39

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 FEB 2021 12:00:20
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

25 FEB 2021 14:04:38

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

28 FEB 2021 05:02:28

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

10 MAR 2021 09:04:51

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 10:25:40

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

22 MAR 2021 11:15:59

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

28 MAR 2021 07:32:37

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 10:49:42

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 16:58:10

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 17:27:37

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 08:25:25

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐
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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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°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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 327

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

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

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

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

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐ 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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐
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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐
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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	21 OCT 2021 23:59
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US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐
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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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°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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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="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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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°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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	17 FEB 2022 23:59
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US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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="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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐ 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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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°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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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="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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐ 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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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°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 ☐

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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"/>

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:10:53

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 05:02:46

US3242017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Mar 2021 14:42:09

Generated On: 09 Jun 2021 16:10:53

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

Visit date (dd MMM yyyy)	03 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:38:36

Generated On: 09 Jun 2021 16:10:53

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) _____

US3242017

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Mar 2021 14:42:09

Generated On: 09 Jun 2021 16:10:53

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.

US3242017

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Mar 2021 14:42:09

Generated On: 09 Jun 2021 16:10:53

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 03 MAR 2021

Collection time (00:00-23:59) 08:30 (24 HR)

Collection date and time (derived) 03 MAR 2021 08:30

US3242017

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 14:42:09

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:53:11

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:53:11

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

Was Contact Attempted?

Yes ☒

No ☐

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

03 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242017

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242017

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Date of Contact	19 OCT 2020
Time of Contact	09:38
Date and Time of Contact (derived)	19 OCT 2020 09:38
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

317 of 2184

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

325 of 2184

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 OCT 2020
------	-------------

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

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

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

Temperature	ND - Not Done
-------------	---------------

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

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

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 2184

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Date of Visit 19 OCT 2020

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

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

Date of Test 19 OCT 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 08 Feb 2021 18:05:08

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

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

Visit date (dd MMM yyyy)	19 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	11:52 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 11:52
Height (xxx.x)	73 in
Weight (xxx.x)	261 lb
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242017

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3242017

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 08 Feb 2021 18:05:08

Generated On: 09 Jun 2021 16:10:53

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3242017

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 08 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242017

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 15:55:21

Generated On: 09 Jun 2021 16:10:53

Date of updated informed consent (dd MMM yyyy) 08 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) 08 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 _____

US3242017

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	08 JAN 2021
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Collection time (00:00-23:59)	14:59 (24 HR)
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Collection date and time (derived)	08 JAN 2021 14:59
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US3242017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 18:05:19

Generated On: 09 Jun 2021 16:10:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	14:54
Collection Date and Time (derived)	08 JAN 2021 14:54

US3242017

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

AEID	USA-US067-2020-MRNA-1273-P30 1000007
Adverse event	ACUTE BRONCHITIS
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)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	19 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	21 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2184

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Feb 2021 18:05:06

Generated On: 09 Jun 2021 16:10:53

SUBJECT CALLED TO REPORT
BEING ADMITTED TO
PIEDMONT ATLANTA AROUND
0200 DUE TO WORSENING OF
SYMPTOMS. SUBJECT IS
HAVING TROUBLE BREATHING
AND COUGH HAS WORSENERED.
HE IS RECEIVING BREATHING
EXERCISES. WE WILL NOT BE
ABLE TO COMPLETE SALIVA
COLLECTIONS OR SYMPTOM
LOG WHILE HE IS IN THE
HOSPITAL. MEDICAL RECORDS
WILL BE REQUESTED

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

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 10 Sep 2020 12:58:07

Generated On: 09 Jun 2021 16:10:53

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

Yes ☒

No ☐

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

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication 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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication TRIAMTERENE/HYDROCHLORO
THIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5/25

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)

356 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	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)		8 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication ZITHROMAX Z - PAK

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

AS DIRECTED

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	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)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication BROMFED
DM(BROMPHENIRAMINE/DEXT
ROMETHORPHAN/PSEUDOEPHE
DRINE)

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 2/10/30

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

If dose unit is Other, specify MG/PER 5 ML

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication PROMETHAZINE/CODEINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 6.25/10

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

If dose unit is Other, specify MG PER 5 ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	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)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 27 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication BRONCHITIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE BRONCHITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 14:50:25

Generated On: 09 Jun 2021 16:10:53

	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)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3242017

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3242017

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

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

US3242017

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 10 Sep 2020 12:58:08

Generated On: 09 Jun 2021 16:10:53

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/OCT/2020 18:31
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

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/OCT/2020 12:20
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

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/OCT/2020 09:04
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

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/NOV/2020 07:57
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

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/NOV/2020 17:05
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

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/NOV/2020 10:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 20 Apr 2021 21:17:34

Generated On: 09 Jun 2021 16:10:53

SAEID	USA-US067-2020-MRNA-1273-P301000007
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	JON
Investigator's Last Name	FINLEY
Site Address: Street	175 COUNTRY CLUB DRIVE 100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:34
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

US3242017 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242017

Form: Participant Creation

Generated On: 09 Jun 2021 16:10:53

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'US3242017'	RWS_ENDPOINT	07 Aug 2020 13:49:39
	ENDPOINT (b) (4)	
	(b) (4)	

US3242017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:03
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:17:07

US3242017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:03
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 13:49:40

US3242017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:03
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	07 Aug 2020 14:17:07

US3242017

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'SCRN'	(b) (4), (b) (6) System	07 Aug 2020 14:17:07

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 13:49:41

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '64'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'YEARS'	(b) (4), (b) (6) System	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '64'	(b) (4), (b) (6) System	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Male (M)'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'I'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:10:53

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:19:47

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'Aug 2020'	(b) (4), (b) (6) System	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '2020'	(b) (4), (b) (6) System	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Amendment 1 (1)'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:09

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:26
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 13:49:40

US3242017

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:10:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'I'	(b) (4), (b) (6) System	07 Aug 2020 14:20:14

US3242017

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:36
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:14

US3242017

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:10:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:54
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:22

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
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)	07 Aug 2020 14:23:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:23:23
Data point term sent to Coder	System	07 Aug 2020 14:21:37
User entered 'Hypertension'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
Signature has been broken.	Donna Toepfer (b) (4)	16 Sep 2020 16:52:51
User entered 'UN UNK 2015' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 16:52:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'Jan 2015'	(b) (4), (b) (6)	
	System	16 Sep 2020 16:52:51
User entered 'Jan 2019'	System	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '2015'	(b) (4), (b) (6)	
	System	16 Sep 2020 16:52:51
User entered '2019'	System	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	07 Aug 2020 14:20:38

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
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.	Coder Import (b) (4)	07 Aug 2020 14:23:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 14:23:24
Data point term sent to Coder	System	07 Aug 2020 14:21:37
User entered 'Benign Prostatic Hyperplasia'	Donna Toepfer (b) (4)	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Un UNK 2015'	Donna Toepfer (b) (4)	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:16
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'Jan 2015'	(b) (4), (b) (6) System	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '2015'	(b) (4), (b) (6) System	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	07 Aug 2020 14:21:08

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User closed query 'Per CDM RQ: Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:23:56
Query 'Per CDM RQ: Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. Thank you!' answered with 'confirm, no meds for this condition' (Site from DM).	Donna Toepfer (b) (4)	16 Dec 2020 12:53:54
User opened query 'Per CDM RQ: Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 11:10:25
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and 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)	16 Dec 2020 11:09:12
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and 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 'no meds taken for this condition' (Site from DM).	Donna Toepfer (b) (4)	28 Nov 2020 16:17:29

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and 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)	27 Nov 2020 15:52:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 16:27:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Nov 2020 16:27:02
Data point term sent to Coder	System	20 Nov 2020 14:15:58
User entered 'Obesity'	Donna Toepfer (b) (4)	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Un UNK 2020'	Donna Toepfer (b) (4)	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '0'	Donna Toepfer (b) (4)	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Donna Toepfer (b) (4)	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '0'	Donna Toepfer (b) (4)	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'Jan 2020'	(b) (4), (b) (6) System	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '2020'	(b) (4), (b) (6) System	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	20 Nov 2020 14:15:33

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '08:54'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '7 Aug 2020 08:54'	(b) (4), (b) (6) System	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '73' in	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19
DataPoint set to visible.	System	07 Aug 2020 14:20:14

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '261' lb	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19
DataPoint set to visible.	System	07 Aug 2020 14:20:14

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
Amendment Manager: User entered '34.50680'	(b) (4), (b) (6)	
User entered '34.5'	System	16 Sep 2020 23:46:58
DataPoint set to visible.	System	07 Aug 2020 14:23:19
	System	07 Aug 2020 14:20:14

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'kg/m2'	(b) (4), (b) (6)	
	System	07 Aug 2020 14:23:19
DataPoint set to visible.	System	07 Aug 2020 14:20:14

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:19:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 11:51:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:28
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:51:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 11:51:10
User entered '97.1' (non-conformant).	Donna Toepfer (b) (4)	31 Aug 2020 11:51:10
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:50:25
User entered '97.1' F	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:10
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:10
User entered '60'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'bpm'	(b) (4), (b) (6) System	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:10
User entered '18'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:10
User entered '132'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'mmHg'	(b) (4), (b) (6) System	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:51
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:10
User entered '84'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'mmHg'	(b) (4), (b) (6) System	07 Aug 2020 14:23:19

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:25:22

US3242017

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:25:22

US3242017

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:27

US3242017

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:01
	(b) (4), (b) (6)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		11 Sep 2020 17:25:54
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 12:54:50
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 14:23:27

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

[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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

[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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Interacts with public daily (b) (6) '	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'I'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:10:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:44:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:24:32

US3242017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:13
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:44

US3242017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:58:52
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Nov 2020 12:43:32
Signature has been broken.	Donna Toepfer (b) (4)	10 Nov 2020 12:43:32
User entered '07 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:43:32
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:13
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:44

US3242017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[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 16:34:21
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:13
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	07 Aug 2020 14:24:44

US3242017

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'VISIT1'	System	07 Aug 2020 14:24:44

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 14:29:22

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:47:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:47:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 14:29:22
User entered '143121' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 14:29:22

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 15:53:54
User closed query 'According to source this subject was Randomized under incorrect stratification (e.g.subject assigned to wrong stratum). Please respond Yes/No to this query regarding this PD per protocol.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 14:41:25
Query 'According to source this subject was Randomized under incorrect stratification (e.g.subject assigned to wrong stratum). Please respond Yes/No to this query regarding this PD per protocol.' answered with 'confirm PD' (Site from CRA).	Donna Toepfer (b) (4)	22 Oct 2020 14:34:50
User opened query 'According to source this subject was Randomized under incorrect stratification (e.g.subject assigned to wrong stratum). Please respond Yes/No to this query regarding this PD per protocol.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:19:09
Protocol deviation created: Randomized under incorrect stratification Class: Other Code: Deviation.	(b) (4), (b) (6)	01 Oct 2020 17:03:27
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'not at risk, this was corrected in endpoint' (Site from System).	Donna Toepfer (b) (4)	01 Oct 2020 11:41:58
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:15:41
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:15:40
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	07 Aug 2020 14:29:22

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	07 Aug 2020 14:29:22

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

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 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:25:03

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

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 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:25:03

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:25:03

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:25:03

US3242017

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:10:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:21
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:25:03

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:29
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:52:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:01
User entered '73' in	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:38
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:14
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' canceled (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:10
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:06

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Weight

Audit	User	Time (GMT)
User entered '261' lb	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:29
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:52:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:01
User entered '73' in	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:38
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:14
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' canceled (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:10
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:06

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Weight

Audit	User	Time (GMT)
User entered '261' lb	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:30:18
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 21:57:02
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 21:57:02
	(b) (4)	
User entered '07 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:57:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '08:54'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '07 Aug 2020 08:54'	System	19 Nov 2020 21:57:02
User entered '7 Aug 2020 08:54'	System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '97.1' F	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '60'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'bpm'	System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '18'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'breaths/min'	(b) (4), (b) (6)	07 Aug 2020 22:49:44
	System	

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '132'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '84'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:29
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:52:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:01
User entered '73' in	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:26:38
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 11:51:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 11:51:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:14
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' canceled (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:10
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:51:06

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:10:53

Weight

Audit	User	Time (GMT)
User entered '261' lb	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:30:18
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 21:57:02
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 21:57:02
	(b) (4)	
User entered '07 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:57:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 07:36:09
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol should be 30 mins' (Site from System).	Donna Toepfer (b) (4)	07 Aug 2020 22:49:51
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 22:49:44
User entered '11:30'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '07 Aug 2020 11:30'	System	19 Nov 2020 21:57:02
User entered '7 Aug 2020 11:30'	System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '97.1' F	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '60'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'bpm'	System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '18'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'breaths/min'	(b) (4), (b) (6)	07 Aug 2020 22:49:44
	System	

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '122'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:29:41
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '86'	Donna Toepfer (b) (4)	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	07 Aug 2020 22:49:44

US3242017

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:02
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:32:47

US3242017

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:02
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:32:47

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	07 Aug 2020 15:03:51
	System	

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '10:49'	Donna Toepfer (b) (4)	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered '7 Aug 2020 10:49'	(b) (4), (b) (6)	07 Aug 2020 15:03:51
	System	

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:09
User entered 'ONCE'	System	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:33:56

US3242017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 21:58:08
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 21:58:08
	(b) (4)	
User entered '07 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:58:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:30:14
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 07AUG2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:30:45
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 07AUG2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'shipped 8/7/2020 Fed Ex tracking 9069 0787 1095' (Site from DM).	Susan Jones (b) (4)	06 Oct 2020 19:47:11
	(b) (4)	
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 07AUG2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:31:30
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 14:33:56

US3242017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '10:16'	Donna Toepfer (b) (4)	07 Aug 2020 14:33:56

US3242017

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '07 Aug 2020 10:16'	System	19 Nov 2020 21:58:08
User entered '7 Aug 2020 10:16'	System	07 Aug 2020 14:33:56

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 21:58:19
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 21:58:19
	(b) (4)	
User entered '07 Aug 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:58:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:30:19
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '7 Aug 2020'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:19
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:19
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '10:08'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '07 Aug 2020 10:08'	System	19 Nov 2020 21:58:19
User entered '7 Aug 2020 10:08'	System	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:19
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:19
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 14:34:52

US3242017

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 14:34:52
	System	

US3242017

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:30:23
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 14:34:57

US3242017

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	(b) (4), (b) (6)	07 Aug 2020 14:34:57
	System	

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:29:16', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6bfcc10f-a3d8-4d77-a0be-634f8a0bfe4b' User entered 'Yes (Y)'	System	07 Aug 2020 15:32:28
	System	07 Aug 2020 15:32:28

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:14', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6bfcc10f-a3d8-4d77-a0be-634f8a0bfe4b' User entered '97.1'	(b) (4), (b) (6) System	07 Aug 2020 15:32:28
	System	07 Aug 2020 15:32:28

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:19', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6bfcc10f-a3d8-4d77-a0be-634f8a0bfe4b' User entered 'No (N)'	(b) (4), (b) (6) System	07 Aug 2020 15:32:28
	System	07 Aug 2020 15:32:28

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:25', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6bfcc10f-a3d8-4d77-a0be-634f8a0bfe4b' User entered '07 Aug 2020 11:32'	(b) (4), (b) (6) System	07 Aug 2020 15:32:28
	System	07 Aug 2020 15:32:28

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 11:09'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 13:39'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:40:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'dad30d06-9ddc-4c03-8ecc-02c01c045fd2'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	08 Aug 2020 02:43:43

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:43:32', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'dad30d06-9ddc-4c03-8ecc-02c01c045fd2' User entered '97.4'	(b) (4), (b) (6) System	08 Aug 2020 02:43:43
	System	08 Aug 2020 02:43:43

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:43:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'dad30d06-9ddc-4c03-8ecc-02c01c045fd2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Aug 2020 02:43:43

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:43:41', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'dad30d06-9ddc-4c03-8ecc-02c01c045fd2'	(b) (4), (b) (6)	
User entered '07 Aug 2020 22:43'	System	08 Aug 2020 02:43:43

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 14:34'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 2'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:56:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '027a6fdf-1fd5-4900-95e1-d55b17ad3048'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	09 Aug 2020 02:56:25

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:56:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '027a6fdf-1fd5-4900-95e1-d55b17ad3048' User entered '97.5'	(b) (4), (b) (6) System	09 Aug 2020 02:56:25
	System	09 Aug 2020 02:56:25

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:56:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '027a6fdf-1fd5-4900-95e1-d55b17ad3048'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 02:56:25

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:56:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '027a6fdf-1fd5-4900-95e1-d55b17ad3048'	(b) (4), (b) (6)	
User entered '08 Aug 2020 22:56'	System	09 Aug 2020 02:56:25

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 3'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:55:57', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7d20d74f-1fed-4df3-bb7f-1fb9adf58402' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Aug 2020 00:58:03
	System	10 Aug 2020 00:58:03

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:57:52', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7d20d74f-1fed-4df3-bb7f-1fb9adf58402' User entered '97.6'	(b) (4), (b) (6) System	10 Aug 2020 00:58:03
	System	10 Aug 2020 00:58:03

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:57:54', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7d20d74f-1fed-4df3-bb7f-1fb9adf58402'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Aug 2020 00:58:03

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:57:58', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7d20d74f-1fed-4df3-bb7f-1fb9adf58402'	(b) (4), (b) (6) System	10 Aug 2020 00:58:03
User entered '09 Aug 2020 20:57'	System	10 Aug 2020 00:58:03

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 4'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8234f944-13a9-457a-80b8-de9a6cf96fd3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Aug 2020 15:42:20
	System	11 Aug 2020 15:42:20

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8234f944-13a9-457a-80b8-de9a6cf96fd3' User entered '98.1'	(b) (4), (b) (6) System	11 Aug 2020 15:42:20
	System	11 Aug 2020 15:42:20

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8234f944-13a9-457a-80b8-de9a6cf96fd3'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Aug 2020 15:42:20

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8234f944-13a9-457a-80b8-de9a6cf96fd3'	(b) (4), (b) (6) System	11 Aug 2020 15:42:20
User entered '11 Aug 2020 11:42'	System	11 Aug 2020 15:42:20

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 5'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:20:54', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4b8a7171-f195-4c7a-a945-de7a43b4c667' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:13
	System	11 Aug 2020 21:21:13

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:03', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4b8a7171-f195-4c7a-a945-de7a43b4c667' User entered '98.0'	(b) (4), (b) (6) System	11 Aug 2020 21:21:13
	System	11 Aug 2020 21:21:13

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:05', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4b8a7171-f195-4c7a-a945-de7a43b4c667'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Aug 2020 21:21:13

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4b8a7171-f195-4c7a-a945-de7a43b4c667'	(b) (4), (b) (6)	
User entered '11 Aug 2020 17:21'	System	11 Aug 2020 21:21:13

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 6'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:17:55', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c3e8cf-d090-4c48-a5d9-93791b7eddc8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:10
	System	13 Aug 2020 02:18:10

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:02', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c3e8cf-d090-4c48-a5d9-93791b7eddc8' User entered '98.1'	(b) (4), (b) (6) System	13 Aug 2020 02:18:10
	System	13 Aug 2020 02:18:10

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c3e8cf-d090-4c48-a5d9-93791b7eddc8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Aug 2020 02:18:10

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:07', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c3e8cf-d090-4c48-a5d9-93791b7eddc8' User entered '12 Aug 2020 22:18'	(b) (4), (b) (6) System	13 Aug 2020 02:18:10
	System	13 Aug 2020 02:18:10

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 7'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:46:44', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c52e65-de58-4410-9209-eef399f89338' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Aug 2020 03:46:55
	System	14 Aug 2020 03:46:55

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:46:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c52e65-de58-4410-9209-eef399f89338' User entered '97.7'	(b) (4), (b) (6) System	14 Aug 2020 03:46:55
	System	14 Aug 2020 03:46:55

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:46:51', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c52e65-de58-4410-9209-eef399f89338'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Aug 2020 03:46:55

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:46:53', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '31c52e65-de58-4410-9209-eef399f89338' User entered '13 Aug 2020 23:46'	(b) (4), (b) (6) System	14 Aug 2020 03:46:55
	System	14 Aug 2020 03:46:55

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '634878b1-7321-455a-88c2-bb259d974f8f' User entered 'None (1)'	(b) (4), (b) (6) System	07 Aug 2020 15:32:58
	System	07 Aug 2020 15:32:58

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:44', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '634878b1-7321-455a-88c2-bb259d974f8f' User entered 'No (N)'	(b) (4), (b) (6) System	07 Aug 2020 15:32:58
	System	07 Aug 2020 15:32:58

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:47', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '634878b1-7321-455a-88c2-bb259d974f8f' User entered 'No (N)'	(b) (4), (b) (6) System	07 Aug 2020 15:32:58
	System	07 Aug 2020 15:32:58

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:51', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '634878b1-7321-455a-88c2-bb259d974f8f' User entered 'None (1)'	(b) (4), (b) (6) System	07 Aug 2020 15:32:58
	System	07 Aug 2020 15:32:58

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:32:56', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '634878b1-7321-455a-88c2-bb259d974f8f' User entered '07 Aug 2020 11:32'	(b) (4), (b) (6) System	07 Aug 2020 15:32:58
	System	07 Aug 2020 15:32:58

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 11:09'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 13:39'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:43:51', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0891b94b-980a-46a6-b2a4-6e7d0853545d' User entered 'None (1)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:26
	System	08 Aug 2020 02:44:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:43:53', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0891b94b-980a-46a6-b2a4-6e7d0853545d' User entered 'No (N)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:26
	System	08 Aug 2020 02:44:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:06', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0891b94b-980a-46a6-b2a4-6e7d0853545d' User entered 'No (N)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:26
	System	08 Aug 2020 02:44:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:16', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0891b94b-980a-46a6-b2a4-6e7d0853545d' User entered 'None (1)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:26
	System	08 Aug 2020 02:44:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0891b94b-980a-46a6-b2a4-6e7d0853545d' User entered '07 Aug 2020 22:44'	(b) (4), (b) (6) System	08 Aug 2020 02:44:26
	System	08 Aug 2020 02:44:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 14:34'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 2'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:56:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e82bb488-e2b3-4d16-81ff-90f823e0013d'	(b) (4), (b) (6)	
	System	09 Aug 2020 02:58:21
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 02:58:21

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:57:01', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e82bb488-e2b3-4d16-81ff-90f823e0013d' User entered 'No (N)'	(b) (4), (b) (6) System	09 Aug 2020 02:58:21
	System	09 Aug 2020 02:58:21

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:57:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e82bb488-e2b3-4d16-81ff-90f823e0013d' User entered 'No (N)'	(b) (4), (b) (6) System	09 Aug 2020 02:58:21
	System	09 Aug 2020 02:58:21

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:58:01', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e82bb488-e2b3-4d16-81ff-90f823e0013d'	(b) (4), (b) (6)	
User entered 'None (1)'	System	09 Aug 2020 02:58:21

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:58:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e82bb488-e2b3-4d16-81ff-90f823e0013d' User entered '08 Aug 2020 22:58'	(b) (4), (b) (6) System	09 Aug 2020 02:58:21
	System	09 Aug 2020 02:58:21

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 3'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:05', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7c90cc24-7988-40ee-8724-45e82e3abc2b' User entered 'None (1)'	(b) (4), (b) (6) System	10 Aug 2020 00:58:24
	System	10 Aug 2020 00:58:24

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:07', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7c90cc24-7988-40ee-8724-45e82e3abc2b' User entered 'No (N)'	(b) (4), (b) (6) System	10 Aug 2020 00:58:24
	System	10 Aug 2020 00:58:24

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7c90cc24-7988-40ee-8724-45e82e3abc2b' User entered 'No (N)'	(b) (4), (b) (6) System	10 Aug 2020 00:58:24
	System	10 Aug 2020 00:58:24

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:17', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7c90cc24-7988-40ee-8724-45e82e3abc2b' User entered 'None (1)'	(b) (4), (b) (6) System	10 Aug 2020 00:58:24
	System	10 Aug 2020 00:58:24

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:19', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7c90cc24-7988-40ee-8724-45e82e3abc2b' User entered '09 Aug 2020 20:58'	(b) (4), (b) (6) System	10 Aug 2020 00:58:24
	System	10 Aug 2020 00:58:24

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 4'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:22', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9f702f71-612f-419f-8de8-08afd2713bc1'	(b) (4), (b) (6)	
	System	11 Aug 2020 15:42:33
User entered 'None (1)'	System	11 Aug 2020 15:42:33

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9f702f71-612f-419f-8de8-08afd2713bc1' User entered 'No (N)'	(b) (4), (b) (6) System	11 Aug 2020 15:42:33
	System	11 Aug 2020 15:42:33

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9f702f71-612f-419f-8de8-08afd2713bc1' User entered 'No (N)'	(b) (4), (b) (6) System	11 Aug 2020 15:42:33
	System	11 Aug 2020 15:42:33

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:29', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9f702f71-612f-419f-8de8-08afd2713bc1'	(b) (4), (b) (6)	11 Aug 2020 15:42:33
User entered 'None (1)'	System	11 Aug 2020 15:42:33

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:32', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9f702f71-612f-419f-8de8-08afd2713bc1' User entered '11 Aug 2020 11:42'	(b) (4), (b) (6) System	11 Aug 2020 15:42:33
	System	11 Aug 2020 15:42:33

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 5'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c1fc7f38-09df-4fbd-9542-41555e9162ac'	(b) (4), (b) (6)	
	System	11 Aug 2020 21:21:40
User entered 'None (1)'	System	11 Aug 2020 21:21:40

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c1fc7f38-09df-4fbd-9542-41555e9162ac'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Aug 2020 21:21:40

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c1fc7f38-09df-4fbd-9542-41555e9162ac'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Aug 2020 21:21:40

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:29', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c1fc7f38-09df-4fbd-9542-41555e9162ac'	(b) (4), (b) (6)	
	System	11 Aug 2020 21:21:40
User entered 'None (1)'	System	11 Aug 2020 21:21:40

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c1fc7f38-09df-4fbd-9542-41555e9162ac'	(b) (4), (b) (6) System	11 Aug 2020 21:21:40
User entered '11 Aug 2020 17:21'	System	11 Aug 2020 21:21:40

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 6'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4f20152e-196d-496e-92a5-6c66498a082e' User entered 'None (1)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:26
	System	13 Aug 2020 02:18:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4f20152e-196d-496e-92a5-6c66498a082e' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:26
	System	13 Aug 2020 02:18:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:16', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4f20152e-196d-496e-92a5-6c66498a082e' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:26
	System	13 Aug 2020 02:18:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4f20152e-196d-496e-92a5-6c66498a082e' User entered 'None (1)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:26
	System	13 Aug 2020 02:18:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:21', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '4f20152e-196d-496e-92a5-6c66498a082e' User entered '12 Aug 2020 22:18'	(b) (4), (b) (6) System	13 Aug 2020 02:18:26
	System	13 Aug 2020 02:18:26

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 7'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:46:58', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ca54a1e3-2abb-4658-96d9-9c619d8eb6bd' User entered 'None (1)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:13
	System	14 Aug 2020 03:47:13

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ca54a1e3-2abb-4658-96d9-9c619d8eb6bd' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:13
	System	14 Aug 2020 03:47:13

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:02', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ca54a1e3-2abb-4658-96d9-9c619d8eb6bd' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:13
	System	14 Aug 2020 03:47:13

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ca54a1e3-2abb-4658-96d9-9c619d8eb6bd' User entered 'None (1)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:13
	System	14 Aug 2020 03:47:13

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ca54a1e3-2abb-4658-96d9-9c619d8eb6bd' User entered '13 Aug 2020 23:47'	(b) (4), (b) (6) System	14 Aug 2020 03:47:13
	System	14 Aug 2020 03:47:13

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'None (0)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'None (0)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'None (0)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:22', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'None (0)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'None (0)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'None (0)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered 'No (N)'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T11:33:34', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '60aa357c-d3f1-4140-8210-bc2863bdc81b' User entered '07 Aug 2020 11:33'	(b) (4), (b) (6) System	07 Aug 2020 15:33:37
	System	07 Aug 2020 15:33:37

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 11:09'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 13:39'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:28', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:34', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:35', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:39', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered 'No (N)'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-07T22:44:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0c197fb2-0c5d-4b95-a338-f5dc6f2ddf24' User entered '07 Aug 2020 22:44'	(b) (4), (b) (6) System	08 Aug 2020 02:44:49
	System	08 Aug 2020 02:44:49

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '07 Aug 2020 14:34'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 2'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:58:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 03:00:18
	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:59:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 03:00:18
	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:59:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 03:00:18
	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T22:59:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 03:00:18
	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T23:00:03', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 03:00:18
	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T23:00:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 03:00:18
	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T23:00:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-08T23:00:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7a90dce1-b1ac-45f2-8c35-e0f7ce7c57b6'	(b) (4), (b) (6)	
User entered '08 Aug 2020 23:00'	System	09 Aug 2020 03:00:18

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 3'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:25', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:28', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:30', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:33', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:35', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-09T20:58:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1f6cc787-be87-4ff7-bc03-2edf6b66ed96'	(b) (4), (b) (6)	
User entered '09 Aug 2020 20:58'	System	10 Aug 2020 00:58:41

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 4'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'None (0)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:39', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'None (0)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:41', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'None (0)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'None (0)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:45', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'None (0)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'None (0)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T11:42:52', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '47fe1f54-df39-4549-b8bc-6d6ad2e02c95'	(b) (4), (b) (6)	
	System	11 Aug 2020 15:42:53
User entered '11 Aug 2020 11:42'	System	11 Aug 2020 15:42:53

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 5'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:41', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:42', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:45', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:47', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:51', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377'	(b) (4), (b) (6)	
User entered 'No (N)'	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-11T17:21:54', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '425f2a9f-4ac2-4a70-828e-4bb5ad908377' User entered '11 Aug 2020 17:21'	(b) (4), (b) (6) System	11 Aug 2020 21:21:56
	System	11 Aug 2020 21:21:56

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 6'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:28', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:30', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:33', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:35', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-12T22:18:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '9096121c-29d0-4057-a449-d68e244478c9' User entered '12 Aug 2020 22:18'	(b) (4), (b) (6) System	13 Aug 2020 02:18:42
	System	13 Aug 2020 02:18:42

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 7'	System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:16', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:19', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:22', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-08-13T23:47:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e9fe85b8-4db5-4fc6-9d3f-687b01ad06f9' User entered '13 Aug 2020 23:47'	(b) (4), (b) (6) System	14 Aug 2020 03:47:29
	System	14 Aug 2020 03:47:29

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:00
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Aug 2020 23:11:43

US3242017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:00
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '14 Aug 2020'	Donna Toepfer (b) (4)	14 Aug 2020 23:11:43

US3242017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:00
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	14 Aug 2020 23:11:43

US3242017

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:00
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	14 Aug 2020 23:11:43

US3242017

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	14 Aug 2020 23:11:34

US3242017

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	14 Aug 2020 23:11:34

US3242017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 18:16:55

US3242017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '21 Aug 2020'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 18:16:55

US3242017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 18:16:55

US3242017

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:14
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Grace Newville (b) (4) (b) (4)	21 Aug 2020 18:16:55

US3242017

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:19
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	21 Aug 2020 18:16:47

US3242017

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 18:16:47
	System	

US3242017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:32
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:01:01

US3242017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:32
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 19:01:01

US3242017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:32
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 19:01:01

US3242017

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:32
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:01:01

US3242017

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:31:37
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	31 Aug 2020 19:33:27

US3242017

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	31 Aug 2020 19:33:27

US3242017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Sep 2020 12:54:50

US3242017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Donna Toepfer (b) (4)	08 Sep 2020 12:54:50

US3242017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[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 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	08 Sep 2020 12:54:50

US3242017

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'VISIT2'	System	08 Sep 2020 12:54:50

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 21:59:58
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:59:58
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User closed query 'Per CDM: Please review and update 'Time of assessment ' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc)' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:28:36
Query 'Per CDM: Please review and update 'Time of assessment ' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc)' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	18 Nov 2020 12:59:26
Signature has been broken.	Donna Toepfer (b) (4)	18 Nov 2020 12:59:18
User entered '08:25' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Nov 2020 12:59:18
User opened query 'Per CDM: Please review and update 'Time of assessment ' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc)' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:29:09
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8:25'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '08 Sep 2020 08:25'	System	19 Nov 2020 21:59:58
User entered '8 Sep 2020 08:25'	System	18 Nov 2020 12:59:18
User entered '8 Sep 2020 8:25'	System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '97.2' F	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '60'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'bpm'	System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '12'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '112'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6)	08 Sep 2020 15:09:25
	System	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '70'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 21:59:58
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:59:58
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User closed query 'Per CDM: Please review and update 'Time of assessment ' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc)' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:29:17
Query 'Per CDM: Please review and update 'Time of assessment ' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc)' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	18 Nov 2020 12:59:43
Signature has been broken.	Donna Toepfer (b) (4)	18 Nov 2020 12:59:37
User entered '09:57' reason for change: Data Entry Error	Donna Toepfer (b) (4)	18 Nov 2020 12:59:37
User opened query 'Per CDM: Please review and update 'Time of assessment ' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc)' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:30:45
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '9:57'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '08 Sep 2020 09:57'	System	19 Nov 2020 21:59:58
User entered '8 Sep 2020 09:57'	System	18 Nov 2020 12:59:37
User entered '8 Sep 2020 9:57'	System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '97.4' F	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '64'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'bpm'	System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '12'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'breaths/min'	(b) (4), (b) (6)	08 Sep 2020 15:09:25
	System	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '116'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '72'	Erynn McKinley (b) (4)	08 Sep 2020 15:09:25
	(b) (4)	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	08 Sep 2020 15:09:25

US3242017

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:04

US3242017

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 12:55:04

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	08 Sep 2020 13:33:49
	System	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Donna Toepfer (b) (4)	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '09:27'	Donna Toepfer (b) (4)	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered '8 Sep 2020 09:27'	(b) (4), (b) (6)	08 Sep 2020 13:33:49
	System	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'ONCE'	System	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:10:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:24

US3242017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 22:00:32
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 22:00:32
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:24

US3242017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '08:50'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:24

US3242017

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '08 Sep 2020 08:50'	System	19 Nov 2020 22:00:32
User entered '8 Sep 2020 08:50'	System	08 Sep 2020 12:55:24

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
Signature has been broken.	Erynn McKinley (b) (4)	19 Nov 2020 22:00:14
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 22:00:14
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '08:40'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '08 Sep 2020 08:40'	System	19 Nov 2020 22:00:14
User entered '8 Sep 2020 08:40'	System	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	08 Sep 2020 12:55:44

US3242017

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 12:55:44
	System	

US3242017

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Sep 2020 12:55:53

US3242017

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	08 Sep 2020 12:55:53

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:00:55', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '12c9b7b7-6c20-4d08-9fd4-b665b02f5a74' User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:13
	System	08 Sep 2020 14:01:13

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '12c9b7b7-6c20-4d08-9fd4-b665b02f5a74' User entered '97.4'	(b) (4), (b) (6) System	08 Sep 2020 14:01:13
	System	08 Sep 2020 14:01:13

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:03', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '12c9b7b7-6c20-4d08-9fd4-b665b02f5a74' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:13
	System	08 Sep 2020 14:01:13

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '12c9b7b7-6c20-4d08-9fd4-b665b02f5a74' User entered '08 Sep 2020 10:01'	(b) (4), (b) (6) System	08 Sep 2020 14:01:13
	System	08 Sep 2020 14:01:13

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 09:47'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 12:17'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a88b2215-150d-41c6-be98-adc5b3701a0b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a88b2215-150d-41c6-be98-adc5b3701a0b' User entered '98.9'	(b) (4), (b) (6) System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a88b2215-150d-41c6-be98-adc5b3701a0b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted and conmed recorded' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 12:17:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a88b2215-150d-41c6-be98-adc5b3701a0b' User entered '1'	Grace Newville (b) (4) (b) (4)	09 Sep 2020 14:38:02
	System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a88b2215-150d-41c6-be98-adc5b3701a0b' User entered '0'	(b) (4), (b) (6) System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a88b2215-150d-41c6-be98-adc5b3701a0b' User entered '09 Sep 2020 07:09'	(b) (4), (b) (6) System	09 Sep 2020 11:09:26
	System	09 Sep 2020 11:09:26

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 13:12'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 2'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:37:47', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '355519df-2607-4316-a1a5-796a3e57db56' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Sep 2020 10:38:02
	System	10 Sep 2020 10:38:02

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:37:53', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '355519df-2607-4316-a1a5-796a3e57db56' User entered '98.6'	(b) (4), (b) (6) System	10 Sep 2020 10:38:02
	System	10 Sep 2020 10:38:02

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:37:57', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '355519df-2607-4316-a1a5-796a3e57db56'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Sep 2020 10:38:02

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '355519df-2607-4316-a1a5-796a3e57db56' User entered '10 Sep 2020 06:38'	(b) (4), (b) (6) System	10 Sep 2020 10:38:02
	System	10 Sep 2020 10:38:02

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 3'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 4'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '99f4d115-a7d6-4c29-8bc2-b449a0e61e47'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Sep 2020 13:14:36

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:17', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '99f4d115-a7d6-4c29-8bc2-b449a0e61e47' User entered '98.5'	(b) (4), (b) (6) System	12 Sep 2020 13:14:36
	System	12 Sep 2020 13:14:36

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:20', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '99f4d115-a7d6-4c29-8bc2-b449a0e61e47'	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Sep 2020 13:14:36

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:25', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '99f4d115-a7d6-4c29-8bc2-b449a0e61e47'	(b) (4), (b) (6)	
User entered '12 Sep 2020 09:14'	System	12 Sep 2020 13:14:36

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 5'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:19', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e3bb503-b48d-460d-ba57-756af8829c19' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 16:01:37
	System	12 Sep 2020 16:01:37

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e3bb503-b48d-460d-ba57-756af8829c19' User entered '98.4'	(b) (4), (b) (6) System	12 Sep 2020 16:01:37
	System	12 Sep 2020 16:01:37

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:29', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e3bb503-b48d-460d-ba57-756af8829c19' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 16:01:37
	System	12 Sep 2020 16:01:37

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:32', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e3bb503-b48d-460d-ba57-756af8829c19' User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	12 Sep 2020 16:01:37
	System	12 Sep 2020 16:01:37

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 6'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:34', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '56653332-7e77-44bd-bb03-70e13001ad6f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Sep 2020 17:29:45
	System	13 Sep 2020 17:29:45

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:38', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '56653332-7e77-44bd-bb03-70e13001ad6f' User entered '98.1'	(b) (4), (b) (6) System	13 Sep 2020 17:29:45
	System	13 Sep 2020 17:29:45

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '56653332-7e77-44bd-bb03-70e13001ad6f' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 17:29:45
	System	13 Sep 2020 17:29:45

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '56653332-7e77-44bd-bb03-70e13001ad6f' User entered '13 Sep 2020 13:29'	(b) (4), (b) (6) System	13 Sep 2020 17:29:45
	System	13 Sep 2020 17:29:45

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 7'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c6c723ed-b868-4ff3-8186-bcc994659cef' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 12:00:44
	System	15 Sep 2020 12:00:44

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:35', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c6c723ed-b868-4ff3-8186-bcc994659cef' User entered '98.6'	(b) (4), (b) (6) System	15 Sep 2020 12:00:44
	System	15 Sep 2020 12:00:44

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c6c723ed-b868-4ff3-8186-bcc994659cef' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 12:00:44
	System	15 Sep 2020 12:00:44

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:41', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'c6c723ed-b868-4ff3-8186-bcc994659cef' User entered '15 Sep 2020 08:00'	(b) (4), (b) (6) System	15 Sep 2020 12:00:44
	System	15 Sep 2020 12:00:44

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fe3d3c1c-b8b7-4bf5-bc93-111ab3938857'	(b) (4), (b) (6)	
	System	08 Sep 2020 14:03:14
User entered 'None (1)'	System	08 Sep 2020 14:03:14

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:52', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fe3d3c1c-b8b7-4bf5-bc93-111ab3938857' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 14:03:14
	System	08 Sep 2020 14:03:14

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:58', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fe3d3c1c-b8b7-4bf5-bc93-111ab3938857' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 14:03:14
	System	08 Sep 2020 14:03:14

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:02:01', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fe3d3c1c-b8b7-4bf5-bc93-111ab3938857'	(b) (4), (b) (6)	
	System	08 Sep 2020 14:03:14
User entered 'None (1)'	System	08 Sep 2020 14:03:14

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:03:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fe3d3c1c-b8b7-4bf5-bc93-111ab3938857' User entered '08 Sep 2020 10:03'	(b) (4), (b) (6) System	08 Sep 2020 14:03:14
	System	08 Sep 2020 14:03:14

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 09:47'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 12:17'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7b22a382-ce38-4763-9532-db4e0228b25c'	(b) (4), (b) (6)	
	System	09 Sep 2020 11:10:28
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 11:10:28

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7b22a382-ce38-4763-9532-db4e0228b25c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 11:10:28
	System	09 Sep 2020 11:10:28

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:09:57', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7b22a382-ce38-4763-9532-db4e0228b25c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 11:10:28
	System	09 Sep 2020 11:10:28

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7b22a382-ce38-4763-9532-db4e0228b25c' User entered 'None (1)'	(b) (4), (b) (6) System	09 Sep 2020 11:10:28
	System	09 Sep 2020 11:10:28

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7b22a382-ce38-4763-9532-db4e0228b25c' User entered '09 Sep 2020 07:10'	(b) (4), (b) (6) System	09 Sep 2020 11:10:28
	System	09 Sep 2020 11:10:28

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 13:12'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 2'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '897bb0a8-d404-467b-b5e4-93cf8f7b5bcd'	(b) (4), (b) (6)	
	System	10 Sep 2020 10:38:44
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 10:38:44

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:12', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '897bb0a8-d404-467b-b5e4-93cf8f7b5bcd' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 10:38:44
	System	10 Sep 2020 10:38:44

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:27', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '897bb0a8-d404-467b-b5e4-93cf8f7b5bcd' User entered 'No (N)'	(b) (4), (b) (6) System	10 Sep 2020 10:38:44
	System	10 Sep 2020 10:38:44

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '897bb0a8-d404-467b-b5e4-93cf8f7b5bcd'	(b) (4), (b) (6)	
	System	10 Sep 2020 10:38:44
User entered 'None (1)'	System	10 Sep 2020 10:38:44

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '897bb0a8-d404-467b-b5e4-93cf8f7b5bcd' User entered '10 Sep 2020 06:38'	(b) (4), (b) (6) System	10 Sep 2020 10:38:44
	System	10 Sep 2020 10:38:44

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 3'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

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)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 4'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ab466084-1c5a-4476-8f91-385e7989b3cb' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 13:14:48
	System	12 Sep 2020 13:14:48

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:38', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ab466084-1c5a-4476-8f91-385e7989b3cb' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 13:14:48
	System	12 Sep 2020 13:14:48

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ab466084-1c5a-4476-8f91-385e7989b3cb' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 13:14:48
	System	12 Sep 2020 13:14:48

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:42', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ab466084-1c5a-4476-8f91-385e7989b3cb' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 13:14:48
	System	12 Sep 2020 13:14:48

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:45', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ab466084-1c5a-4476-8f91-385e7989b3cb' User entered '12 Sep 2020 09:14'	(b) (4), (b) (6) System	12 Sep 2020 13:14:48
	System	12 Sep 2020 13:14:48

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 5'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:39', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '2cde5e41-f4fa-432c-905f-2b780ac90401' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 16:03:00
	System	12 Sep 2020 16:03:00

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:42', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '2cde5e41-f4fa-432c-905f-2b780ac90401' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 16:03:00
	System	12 Sep 2020 16:03:00

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:45', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '2cde5e41-f4fa-432c-905f-2b780ac90401' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 16:03:00
	System	12 Sep 2020 16:03:00

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:52', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '2cde5e41-f4fa-432c-905f-2b780ac90401' User entered 'None (1)'	(b) (4), (b) (6) System	12 Sep 2020 16:03:00
	System	12 Sep 2020 16:03:00

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:55', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '2cde5e41-f4fa-432c-905f-2b780ac90401' User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	12 Sep 2020 16:03:00
	System	12 Sep 2020 16:03:00

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 6'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '281a18c8-efee-47a9-bfb8-d4f0566b3b89'	(b) (4), (b) (6)	
User entered 'None (1)'	System	13 Sep 2020 17:30:07

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:51', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '281a18c8-efee-47a9-bfb8-d4f0566b3b89' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:07
	System	13 Sep 2020 17:30:07

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:29:54', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '281a18c8-efee-47a9-bfb8-d4f0566b3b89' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:07
	System	13 Sep 2020 17:30:07

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:02', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '281a18c8-efee-47a9-bfb8-d4f0566b3b89'	(b) (4), (b) (6)	
	System	13 Sep 2020 17:30:07
User entered 'None (1)'	System	13 Sep 2020 17:30:07

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '281a18c8-efee-47a9-bfb8-d4f0566b3b89' User entered '13 Sep 2020 13:30'	(b) (4), (b) (6) System	13 Sep 2020 17:30:07
	System	13 Sep 2020 17:30:07

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 7'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:45', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e4c4754-c467-4e58-a095-6b24c6898e96'	(b) (4), (b) (6)	
User entered 'None (1)'	System	15 Sep 2020 12:01:06

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:48', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e4c4754-c467-4e58-a095-6b24c6898e96' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:06
	System	15 Sep 2020 12:01:06

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:50', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e4c4754-c467-4e58-a095-6b24c6898e96' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:06
	System	15 Sep 2020 12:01:06

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:00:57', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e4c4754-c467-4e58-a095-6b24c6898e96'	(b) (4), (b) (6)	
User entered 'None (1)'	System	15 Sep 2020 12:01:06

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:01', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '8e4c4754-c467-4e58-a095-6b24c6898e96' User entered '15 Sep 2020 08:01'	(b) (4), (b) (6) System	15 Sep 2020 12:01:06
	System	15 Sep 2020 12:01:06

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:21', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:25', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:28', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:30', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:32', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'None (0)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:35', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered 'No (N)'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-08T10:01:38', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '09768bc3-3f27-4a09-8a7a-b47cc41e0dda' User entered '08 Sep 2020 10:01'	(b) (4), (b) (6) System	08 Sep 2020 14:01:41
	System	08 Sep 2020 14:01:41

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 09:47'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 12:17'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:33', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 11:11:07
	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:38', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049'	(b) (4), (b) (6)	
User entered 'No interference with activity (1)'	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049'	(b) (4), (b) (6)	
User entered 'Some interference with activity (2)'	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:50', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 11:11:07
	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:53', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 11:11:07
	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:10:58', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049' User entered 'None (0)'	(b) (4), (b) (6) System	09 Sep 2020 11:11:07
	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:11:01', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049' User entered 'No (N)'	(b) (4), (b) (6) System	09 Sep 2020 11:11:07
	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-09T07:11:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '85ba42aa-10e2-4fde-bfd5-39bf925ff049' User entered '09 Sep 2020 07:11'	(b) (4), (b) (6) System	09 Sep 2020 11:11:07
	System	09 Sep 2020 11:11:07

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '08 Sep 2020 13:12'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 2'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:44', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:48', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:50', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52'	(b) (4), (b) (6)	
User entered 'None (0)'	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:52', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 10:39:05
	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:55', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 10:39:05
	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:38:58', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-10T06:39:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '0af30c62-e5b0-48f1-9cfe-b75a9edeff52'	(b) (4), (b) (6)	
User entered '10 Sep 2020 06:39'	System	10 Sep 2020 10:39:05

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '09 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 3'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

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)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 16:58:56

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 4'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:50', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:51', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:53', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:54', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:56', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:14:58', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T09:15:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '779bc51f-560c-4faa-b874-b2c6d4a63500' User entered '12 Sep 2020 09:15'	(b) (4), (b) (6) System	12 Sep 2020 13:15:03
	System	12 Sep 2020 13:15:03

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 5'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:00:59', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 16:04:35
	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:01', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 16:04:35
	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:03', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 16:04:35
	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:06', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 16:04:35
	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 16:04:35
	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 16:04:35
	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962'	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-12T12:01:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1abd5cd-80ce-4767-b1d7-3189fc34a962'	(b) (4), (b) (6)	
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 16:04:35

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 6'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:11', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:14', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:16', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:19', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:22', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 17:30:26
	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-13T13:30:24', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'fdb0a467-4878-4f8c-8039-d192651c07fe'	(b) (4), (b) (6)	
User entered '13 Sep 2020 13:30'	System	13 Sep 2020 17:30:26

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	08 Sep 2020 13:33:49
User entered 'Day 7'	System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:06', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:07', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:09', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:11', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:13', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-09-15T08:01:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '238c7c77-7852-4c8c-8481-77c1a4bcb7d5' User entered '15 Sep 2020 08:01'	(b) (4), (b) (6) System	15 Sep 2020 12:01:21
	System	15 Sep 2020 12:01:21

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:10:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 13:33:49

US3242017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Grace Newville (b) (4)	17 Sep 2020 16:26:41
	(b) (4)	

US3242017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '17 Sep 2020'	Grace Newville (b) (4)	17 Sep 2020 16:26:41
	(b) (4)	

US3242017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	17 Sep 2020 16:26:41
	(b) (4)	

US3242017

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Grace Newville (b) (4)	17 Sep 2020 16:26:41
	(b) (4)	

US3242017

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Grace Newville (b) (4)	17 Sep 2020 16:26:44
	(b) (4)	

US3242017

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	17 Sep 2020 16:26:44

US3242017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Grace Newville (b) (4)	23 Sep 2020 23:24:13
	(b) (4)	

US3242017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '23 Sep 2020'	Grace Newville (b) (4)	23 Sep 2020 23:24:13
	(b) (4)	

US3242017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	23 Sep 2020 23:24:13
	(b) (4)	

US3242017

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Grace Newville (b) (4)	23 Sep 2020 23:24:13
	(b) (4)	

US3242017

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Grace Newville (b) (4)	23 Sep 2020 23:24:17
	(b) (4)	

US3242017

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	23 Sep 2020 23:24:17

US3242017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 18:12:05
	(b) (4)	

US3242017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '29 Sep 2020'	Grace Newville (b) (4)	29 Sep 2020 18:12:05
	(b) (4)	

US3242017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	29 Sep 2020 18:12:05
	(b) (4)	

US3242017

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Grace Newville (b) (4)	29 Sep 2020 18:12:05
	(b) (4)	

US3242017

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 18:12:09
	(b) (4)	

US3242017

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	29 Sep 2020 18:12:09

US3242017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Oct 2020 13:59:42
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '8 Oct 2020'	Erynn McKinley (b) (4)	08 Oct 2020 13:59:42
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[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 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	08 Oct 2020 13:59:42
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'VISIT3'	System	08 Oct 2020 13:59:42

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 22:01:58
	(b) (4)	
User entered '8 Oct 2020'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08:56' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 22:01:58
	(b) (4)	
User entered '8:56'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '08 Oct 2020 08:56'	System	19 Nov 2020 22:01:58
User entered '8 Oct 2020 8:56'	System	08 Oct 2020 14:00:49

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '97.0' F	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '64'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'bpm'	System	08 Oct 2020 14:00:49

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '16'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'breaths/min'	(b) (4), (b) (6)	08 Oct 2020 14:00:49
	System	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '138'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	08 Oct 2020 14:00:49

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '84'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:49
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'mmHg'	(b) (4), (b) (6) System	08 Oct 2020 14:00:49

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'No (N)'	Erynn McKinley (b) (4)	08 Oct 2020 14:00:55
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Erynn McKinley (b) (4)	08 Oct 2020 14:00:55
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Oct 2020 14:01:14
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 22:02:13
	(b) (4)	
User entered '8 Oct 2020'	Erynn McKinley (b) (4)	08 Oct 2020 14:01:14
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '09:45' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 22:02:13
	(b) (4)	
User entered '9:45'	Erynn McKinley (b) (4)	08 Oct 2020 14:01:14
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User entered '08 Oct 2020 09:45'	System	19 Nov 2020 22:02:13
User entered '8 Oct 2020 9:45'	System	08 Oct 2020 14:01:14

US3242017

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Oct 2020 14:01:18
	(b) (4)	

US3242017

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 14:01:18
	System	

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 64'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-08T08:57:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ba882b3b-2b93-4c5e-9459-f2ac02eb99d0'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Oct 2020 12:57:14

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-08T08:57:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ba882b3b-2b93-4c5e-9459-f2ac02eb99d0'	(b) (4), (b) (6)	
	System	08 Oct 2020 12:57:14
User entered 'No (N)'	System	08 Oct 2020 12:57:14

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-08T08:57:12', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'ba882b3b-2b93-4c5e-9459-f2ac02eb99d0' User entered '08 Oct 2020 08:57:12'	(b) (4), (b) (6) System	08 Oct 2020 12:57:14
	System	08 Oct 2020 12:57:14

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 71'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-16T17:52:29', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1c43724-92d9-4822-8c41-f65f50260536'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 21:52:40

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-16T17:52:32', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1c43724-92d9-4822-8c41-f65f50260536'	(b) (4), (b) (6)	
	System	16 Oct 2020 21:52:40
User entered 'No (N)'	System	16 Oct 2020 21:52:40

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-16T17:52:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a1c43724-92d9-4822-8c41-f65f50260536' User entered '16 Oct 2020 17:52:36'	(b) (4), (b) (6) System	16 Oct 2020 21:52:40
	System	16 Oct 2020 21:52:40

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 78'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-24T13:48:44', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '148d145f-c28b-4cf8-91d8-204ecc236f64'	(b) (4), (b) (6)	
	System	24 Oct 2020 17:49:10
User entered 'No (N)'	System	24 Oct 2020 17:49:10

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-24T13:49:04', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '148d145f-c28b-4cf8-91d8-204ecc236f64'	(b) (4), (b) (6)	
	System	24 Oct 2020 17:49:10
User entered 'No (N)'	System	24 Oct 2020 17:49:10

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-10-24T13:49:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '148d145f-c28b-4cf8-91d8-204ecc236f64' User entered '24 Oct 2020 13:49:08'	(b) (4), (b) (6) System	24 Oct 2020 17:49:10
	System	24 Oct 2020 17:49:10

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 92'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-06T12:52:08', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1ba9747b-0644-4410-b9fb-1838dab71b83'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Nov 2020 17:52:16

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-06T12:52:10', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1ba9747b-0644-4410-b9fb-1838dab71b83'	(b) (4), (b) (6)	
User entered 'No (N)'	System	06 Nov 2020 17:52:16

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-06T12:52:14', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1ba9747b-0644-4410-b9fb-1838dab71b83' User entered '06 Nov 2020 12:52:14'	(b) (4), (b) (6) System	06 Nov 2020 17:52:16
	System	06 Nov 2020 17:52:16

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 99'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-11T16:18:30', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6d62a34a-37f4-4db6-a3c3-5c7737c3c0e0' User entered 'No (N)'	(b) (4), (b) (6) System	11 Nov 2020 21:18:38
	System	11 Nov 2020 21:18:38

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-11T16:18:32', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6d62a34a-37f4-4db6-a3c3-5c7737c3c0e0' User entered 'No (N)'	(b) (4), (b) (6) System	11 Nov 2020 21:18:38
	System	11 Nov 2020 21:18:38

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-11T16:18:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '6d62a34a-37f4-4db6-a3c3-5c7737c3c0e0' User entered '11 Nov 2020 16:18:36'	(b) (4), (b) (6) System	11 Nov 2020 21:18:38
	System	11 Nov 2020 21:18:38

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered 'Day 106'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-18T23:32:54', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '961a1091-13f7-4ccc-be45-8ea71b18a33e' User entered 'No (N)'	(b) (4), (b) (6) System	19 Nov 2020 04:33:07
	System	19 Nov 2020 04:33:07

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-18T23:32:57', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '961a1091-13f7-4ccc-be45-8ea71b18a33e'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Nov 2020 04:33:07

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-18T23:33:03', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '961a1091-13f7-4ccc-be45-8ea71b18a33e' User entered '18 Nov 2020 23:33:03'	(b) (4), (b) (6) System	19 Nov 2020 04:33:07
	System	19 Nov 2020 04:33:07

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 15:03:51

US3242017

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:58:56
	(b) (4), (b) (6)	
Data entry locked.	System	07 Aug 2020 15:03:51
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 15:03:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-19T12:22:02', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd4875ff1-174d-4ca1-a46f-0022e4f606c0'	System	19 Nov 2020 17:22:16
User entered 'No (N)'	System	19 Nov 2020 17:22:16

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-19T12:22:07', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd4875ff1-174d-4ca1-a46f-0022e4f606c0'	System	19 Nov 2020 17:22:16
User entered 'No (N)'	System	19 Nov 2020 17:22:16

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-19T12:22:11', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd4875ff1-174d-4ca1-a46f-0022e4f606c0' User entered '19 Nov 2020 12:22:11'	System	19 Nov 2020 17:22:16
	System	19 Nov 2020 17:22:16

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-23T14:37:42', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7e558ac3-3f36-4f33-9181-1014d63b521a' User entered 'No (N)'	System	23 Nov 2020 19:37:51
	System	23 Nov 2020 19:37:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-23T14:37:45', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7e558ac3-3f36-4f33-9181-1014d63b521a' User entered 'No (N)'	System	23 Nov 2020 19:37:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-23T14:37:48', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7e558ac3-3f36-4f33-9181-1014d63b521a' User entered '23 Nov 2020 14:37:48'	System	23 Nov 2020 19:37:51
	System	23 Nov 2020 19:37:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-30T08:33:21', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'b391ea02-7ab1-4e79-b4bb-703e7aa91536'	System	30 Nov 2020 13:34:25
User entered 'No (N)'	System	30 Nov 2020 13:34:25

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-30T08:34:18', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'b391ea02-7ab1-4e79-b4bb-703e7aa91536'	System	30 Nov 2020 13:34:25
User entered 'No (N)'	System	30 Nov 2020 13:34:25

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-11-30T08:34:22', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'b391ea02-7ab1-4e79-b4bb-703e7aa91536' User entered '30 Nov 2020 08:34:22'	System	30 Nov 2020 13:34:25
	System	30 Nov 2020 13:34:25

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-07T09:57:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '63aa4eb5-ace2-44c1-86e8-b3ba7e4298ed' User entered 'No (N)'	System	07 Dec 2020 14:57:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-07T09:57:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '63aa4eb5-ace2-44c1-86e8-b3ba7e4298ed' User entered 'No (N)'	System	07 Dec 2020 14:57:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-07T09:57:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '63aa4eb5-ace2-44c1-86e8-b3ba7e4298ed' User entered '07 Dec 2020 09:57:43'	System	07 Dec 2020 14:57:44
	System	07 Dec 2020 14:57:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-13T00:01:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'f14a736d-31ae-4364-bcbf-ad1535a85783'	System	13 Dec 2020 05:01:53
User entered 'No (N)'	System	13 Dec 2020 05:01:53

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-13T00:01:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'f14a736d-31ae-4364-bcbf-ad1535a85783' User entered 'No (N)'	System	13 Dec 2020 05:01:53
	System	13 Dec 2020 05:01:53

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-13T00:01:34', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'f14a736d-31ae-4364-bcbf-ad1535a85783' User entered '13 Dec 2020 00:01:34'	System	13 Dec 2020 05:01:53
	System	13 Dec 2020 05:01:53

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-21T10:21:33', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '35debe1a-90dc-447d-be1c-cfd3ca3670a2' User entered 'No (N)'	System	21 Dec 2020 15:21:44
	System	21 Dec 2020 15:21:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-21T10:21:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '35debe1a-90dc-447d-be1c-cfd3ca3670a2'	System	21 Dec 2020 15:21:44
User entered 'No (N)'	System	21 Dec 2020 15:21:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-21T10:21:40', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '35debe1a-90dc-447d-be1c-cfd3ca3670a2' User entered '21 Dec 2020 10:21:40'	System	21 Dec 2020 15:21:44
	System	21 Dec 2020 15:21:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-27T14:55:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e5782a88-5785-4baa-8837-b7e43fae4082' User entered 'No (N)'	System	27 Dec 2020 19:55:55
	System	27 Dec 2020 19:55:55

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-27T14:55:49', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e5782a88-5785-4baa-8837-b7e43fae4082' User entered 'No (N)'	System	27 Dec 2020 19:55:55
	System	27 Dec 2020 19:55:55

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2020-12-27T14:55:52', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e5782a88-5785-4baa-8837-b7e43fae4082' User entered '27 Dec 2020 14:55:52'	System	27 Dec 2020 19:55:55
	System	27 Dec 2020 19:55:55

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-03T00:01:23', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '46b2667c-6d58-478b-8e0e-b17a2995fb45' User entered 'No (N)'	System	03 Jan 2021 05:02:01
	System	03 Jan 2021 05:02:01

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-03T00:01:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '46b2667c-6d58-478b-8e0e-b17a2995fb45'	System	03 Jan 2021 05:02:01
User entered 'No (N)'	System	03 Jan 2021 05:02:01

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-03T00:01:29', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '46b2667c-6d58-478b-8e0e-b17a2995fb45' User entered '03 Jan 2021 00:01:29'	System	03 Jan 2021 05:02:01
	System	03 Jan 2021 05:02:01

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-12T15:22:34', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a76990de-227a-4b2e-ba2d-3c0c3ff96b2e' User entered 'No (N)'	System	12 Jan 2021 20:22:45
	System	12 Jan 2021 20:22:45

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-12T15:22:37', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a76990de-227a-4b2e-ba2d-3c0c3ff96b2e' User entered 'No (N)'	System	12 Jan 2021 20:22:45

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-12T15:22:41', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'a76990de-227a-4b2e-ba2d-3c0c3ff96b2e' User entered '12 Jan 2021 15:22:41'	System	12 Jan 2021 20:22:45
	System	12 Jan 2021 20:22:45

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-18T23:29:27', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '48af1738-8f45-4841-a1dc-e70e313ae64d'	System	19 Jan 2021 04:29:38
User entered 'No (N)'	System	19 Jan 2021 04:29:38

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-18T23:29:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '48af1738-8f45-4841-a1dc-e70e313ae64d'	System	19 Jan 2021 04:29:38
User entered 'No (N)'	System	19 Jan 2021 04:29:38

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-18T23:29:36', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '48af1738-8f45-4841-a1dc-e70e313ae64d' User entered '18 Jan 2021 23:29:36'	System	19 Jan 2021 04:29:38
	System	19 Jan 2021 04:29:38

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-26T12:30:26', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd39262c4-a7fb-4a7f-b645-b1c3df06b35a' User entered 'No (N)'	System	26 Jan 2021 17:58:10
	System	26 Jan 2021 17:58:10

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-26T12:30:38', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd39262c4-a7fb-4a7f-b645-b1c3df06b35a'	System	26 Jan 2021 17:58:10
User entered 'No (N)'	System	26 Jan 2021 17:58:10

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-01-26T12:30:42', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd39262c4-a7fb-4a7f-b645-b1c3df06b35a' User entered '26 Jan 2021 12:30:42'	System	26 Jan 2021 17:58:10
	System	26 Jan 2021 17:58:10

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-02T13:33:41', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '19317eca-c47d-4286-86ca-48e41d77133f' User entered 'No (N)'	System	02 Feb 2021 18:33:51
	System	02 Feb 2021 18:33:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-02T13:33:43', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '19317eca-c47d-4286-86ca-48e41d77133f' User entered 'No (N)'	System	02 Feb 2021 18:33:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-02T13:33:46', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '19317eca-c47d-4286-86ca-48e41d77133f' User entered '02 Feb 2021 13:33:46'	System	02 Feb 2021 18:33:51
	System	02 Feb 2021 18:33:51

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-07T00:01:31', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '00e2b732-62d9-40d9-86af-2eb1a4100ecb' User entered 'No (N)'	System	07 Feb 2021 05:02:05
	System	07 Feb 2021 05:02:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-07T00:01:34', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '00e2b732-62d9-40d9-86af-2eb1a4100ecb' User entered 'No (N)'	System	07 Feb 2021 05:02:05
	System	07 Feb 2021 05:02:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-07T00:01:39', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '00e2b732-62d9-40d9-86af-2eb1a4100ecb' User entered '07 Feb 2021 00:01:39'	System	07 Feb 2021 05:02:05
	System	07 Feb 2021 05:02:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-16T12:00:15', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '370d5ae0-95e0-4111-94e9-41052f83d145'	System	16 Feb 2021 17:01:00
User entered 'No (N)'	System	16 Feb 2021 17:01:00

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-16T12:00:17', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '370d5ae0-95e0-4111-94e9-41052f83d145'	System	16 Feb 2021 17:01:00
User entered 'No (N)'	System	16 Feb 2021 17:01:00

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-16T12:00:20', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '370d5ae0-95e0-4111-94e9-41052f83d145'	System	16 Feb 2021 17:01:00
User entered '16 Feb 2021 12:00:20'	System	16 Feb 2021 17:01:00

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-25T09:04:32-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'cd9b87bb-85e2-488d-b3c1-0be3dea4e52c' User entered 'No (N)'	System	26 Feb 2021 06:59:54
	System	26 Feb 2021 06:59:54

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-25T09:04:34-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'cd9b87bb-85e2-488d-b3c1-0be3dea4e52c' User entered 'No (N)'	System	26 Feb 2021 06:59:54
	System	26 Feb 2021 06:59:54

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-25T09:04:38-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'cd9b87bb-85e2-488d-b3c1-0be3dea4e52c'	System	26 Feb 2021 06:59:54
User entered '25 Feb 2021 14:04:38'	System	26 Feb 2021 06:59:54

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-28T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '728d8023-06a1-4fc5-b16c-ac3ccd166063'	System	28 Feb 2021 05:04:18
User entered 'No (N)'	System	28 Feb 2021 05:04:18

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-28T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '728d8023-06a1-4fc5-b16c-ac3ccd166063'	System	28 Feb 2021 05:04:18
User entered 'No (N)'	System	28 Feb 2021 05:04:18

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-28T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '728d8023-06a1-4fc5-b16c-ac3ccd166063' User entered '28 Feb 2021 05:02:28'	System	28 Feb 2021 05:04:18
	System	28 Feb 2021 05:04:18

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-10T09:04:45-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '901c6eca-5e6e-47f6-b627-19aa23371292'	System	10 Mar 2021 14:05:12
User entered 'No (N)'	System	10 Mar 2021 14:05:12

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-10T09:04:48-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '901c6eca-5e6e-47f6-b627-19aa23371292'	System	10 Mar 2021 14:05:12
User entered 'No (N)'	System	10 Mar 2021 14:05:12

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-10T09:04:51-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '901c6eca-5e6e-47f6-b627-19aa23371292' User entered '10 Mar 2021 09:04:51'	System	10 Mar 2021 14:05:12
	System	10 Mar 2021 14:05:12

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-17T10:25:35-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd43a0183-b9c8-4c32-b095-99ccce18d7cd' User entered 'No (N)'	System	17 Mar 2021 14:25:44
	System	17 Mar 2021 14:25:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-17T10:25:37-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd43a0183-b9c8-4c32-b095-99ccce18d7cd' User entered 'No (N)'	System	17 Mar 2021 14:25:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-17T10:25:40-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'd43a0183-b9c8-4c32-b095-99ccce18d7cd' User entered '17 Mar 2021 10:25:40'	System	17 Mar 2021 14:25:44
	System	17 Mar 2021 14:25:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-22T11:15:54-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7f3f5b2b-ceed-46c4-8139-2034a2415b67'	System	22 Mar 2021 15:16:04
User entered 'No (N)'	System	22 Mar 2021 15:16:04

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-22T11:15:56-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7f3f5b2b-ceed-46c4-8139-2034a2415b67'	System	22 Mar 2021 15:16:04
User entered 'No (N)'	System	22 Mar 2021 15:16:04

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-22T11:15:59-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '7f3f5b2b-ceed-46c4-8139-2034a2415b67'	System	22 Mar 2021 15:16:04
User entered '22 Mar 2021 11:15:59'	System	22 Mar 2021 15:16:04

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-28T07:32:32-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '676dd687-20a5-4624-9afa-d6ba63937cab' User entered 'No (N)'	System	28 Mar 2021 11:32:39
	System	28 Mar 2021 11:32:39

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-28T07:32:33-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '676dd687-20a5-4624-9afa-d6ba63937cab' User entered 'No (N)'	System	28 Mar 2021 11:32:39

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-03-28T07:32:37-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '676dd687-20a5-4624-9afa-d6ba63937cab' User entered '28 Mar 2021 07:32:37'	System	28 Mar 2021 11:32:39
	System	28 Mar 2021 11:32:39

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-05T10:49:37-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'b99fb5a4-739f-47c8-b8d2-a9e7e9c3f89e'	System	05 Apr 2021 14:49:44
User entered 'No (N)'	System	05 Apr 2021 14:49:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-05T10:49:39-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'b99fb5a4-739f-47c8-b8d2-a9e7e9c3f89e'	System	05 Apr 2021 14:49:44
User entered 'No (N)'	System	05 Apr 2021 14:49:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-05T10:49:42-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'b99fb5a4-739f-47c8-b8d2-a9e7e9c3f89e'	System	05 Apr 2021 14:49:44
User entered '05 Apr 2021 10:49:42'	System	05 Apr 2021 14:49:44

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-12T16:58:05-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1949451f-8244-4190-a7c3-96158a8d7b0e'	System	12 Apr 2021 20:58:17
User entered 'No (N)'	System	12 Apr 2021 20:58:17

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-12T16:58:07-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1949451f-8244-4190-a7c3-96158a8d7b0e' User entered 'No (N)'	System	12 Apr 2021 20:58:17
	System	12 Apr 2021 20:58:17

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-12T16:58:10-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '1949451f-8244-4190-a7c3-96158a8d7b0e'	System	12 Apr 2021 20:58:17
User entered '12 Apr 2021 16:58:10'	System	12 Apr 2021 20:58:17

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-19T17:27:32-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'afb1ad71-abb3-419d-b326-650b92829705'	System	19 Apr 2021 21:27:42
User entered 'No (N)'	System	19 Apr 2021 21:27:42

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-19T17:27:34-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'afb1ad71-abb3-419d-b326-650b92829705'	System	19 Apr 2021 21:27:42
User entered 'No (N)'	System	19 Apr 2021 21:27:42

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-19T17:27:37-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'afb1ad71-abb3-419d-b326-650b92829705'	System	19 Apr 2021 21:27:42
User entered '19 Apr 2021 17:27:37'	System	19 Apr 2021 21:27:42

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-27T08:25:21-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e1f52781-28da-48a2-b876-8617982a30d6'	System	29 Apr 2021 13:28:49
User entered 'No (N)'	System	29 Apr 2021 13:28:49

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

Have you been exposed to someone with 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 (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-27T08:25:23-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e1f52781-28da-48a2-b876-8617982a30d6'	System	29 Apr 2021 13:28:49
User entered 'No (N)'	System	29 Apr 2021 13:28:49

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-04-27T08:25:25-04:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: 'e1f52781-28da-48a2-b876-8617982a30d6'	System	29 Apr 2021 13:28:49
User entered '27 Apr 2021 08:25:25'	System	29 Apr 2021 13:28:49

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:38:05

US3242017

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:10:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:38:05
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:38:05

US3242017

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:10:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:13:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-28T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '15609d4d-7374-449a-ab9c-3042ea31d8d5'	System	17 Mar 2021 14:25:43
User entered 'No (N)'	System	17 Mar 2021 14:25:43

US3242017

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:10:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:13:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (389D5DC2-91A5-45A5-BA7D-79CB137C1092)', Time: '2021-02-28T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3242017)', ODM File OID: '15609d4d-7374-449a-ab9c-3042ea31d8d5' User entered '28 Feb 2021 05:02:46'	System	17 Mar 2021 14:25:43
	System	17 Mar 2021 14:25:43

US3242017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Nov 2020 22:02:29
	(b) (4)	

US3242017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '6 Nov 2020'	Erynn McKinley (b) (4)	19 Nov 2020 22:02:29
	(b) (4)	

US3242017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	19 Nov 2020 22:02:29
	(b) (4)	

US3242017

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Erynn McKinley (b) (4)	19 Nov 2020 22:02:29
	(b) (4)	

US3242017

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Nov 2020 22:02:36
	(b) (4)	

US3242017

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:34:21
User entered 'I'	System	19 Nov 2020 22:02:36

US3242017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	07 Dec 2020 17:43:16

US3242017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '7 Dec 2020'	Erynn McKinley (b) (4)	07 Dec 2020 17:43:16

US3242017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	07 Dec 2020 17:43:16

US3242017

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Erynn McKinley (b) (4)	07 Dec 2020 17:43:16

US3242017

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	07 Dec 2020 17:43:21

US3242017

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered 'I'	(b) (4), (b) (6) System	07 Dec 2020 17:43:21

US3242017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	04 Jan 2021 17:37:55
	(b) (4)	

US3242017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '4 Jan 2021'	Erynn McKinley (b) (4)	04 Jan 2021 17:37:55
	(b) (4)	

US3242017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	04 Jan 2021 17:37:55
	(b) (4)	

US3242017

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Erynn McKinley (b) (4)	04 Jan 2021 17:37:55
	(b) (4)	

US3242017

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	04 Jan 2021 17:38:01
	(b) (4)	

US3242017

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered 'I'	(b) (4), (b) (6) System	04 Jan 2021 17:38:01

US3242017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Feb 2021 16:56:22
	(b) (4)	

US3242017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '2 Feb 2021'	Erynn McKinley (b) (4)	02 Feb 2021 16:56:22
	(b) (4)	

US3242017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	02 Feb 2021 16:56:22
	(b) (4)	

US3242017

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered empty.	Erynn McKinley (b) (4)	02 Feb 2021 16:56:22
	(b) (4)	

US3242017

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	02 Feb 2021 16:56:25
	(b) (4)	

US3242017

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered 'I'	(b) (4), (b) (6) System	02 Feb 2021 16:56:25

US3242017

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	03 Mar 2021 14:58:57
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered '03 Mar 2021'	Erynn McKinley (b) (4)	03 Mar 2021 14:58:57
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	03 Mar 2021 14:58:57
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered 'VISIT4'	(b) (4), (b) (6) System	03 Mar 2021 14:58:57

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:03:05

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:03:05

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:03:05

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:03:05

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:38:36
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:03:05
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:03:05

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 15:03:35

US3242017

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 15:03:35

US3242017

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered 'No (N)'	Erynn McKinley (b) (4)	03 Mar 2021 14:59:02
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered empty.	Erynn McKinley (b) (4)	03 Mar 2021 14:59:02
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	03 Mar 2021 14:59:14
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered '03 Mar 2021'	Erynn McKinley (b) (4)	03 Mar 2021 14:59:14
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered '08:30'	Erynn McKinley (b) (4)	03 Mar 2021 14:59:14
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered '03 Mar 2021 08:30'	(b) (4), (b) (6) System	03 Mar 2021 14:59:14

US3242017

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:42:09
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	03 Mar 2021 14:59:30
	(b) (4)	

US3242017

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:03:35
User entered 'I'	(b) (4), (b) (6) System	03 Mar 2021 14:59:30

US3242017

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:06
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Apr 2021 15:07:16

US3242017

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:06
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:11
User entered '05 Apr 2021'	Erynn McKinley (b) (4)	05 Apr 2021 15:07:16

US3242017

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:06
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:11
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	05 Apr 2021 15:07:16

US3242017

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:06
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:11
User entered empty.	Erynn McKinley (b) (4)	05 Apr 2021 15:07:16

US3242017

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:06
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:53:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Apr 2021 15:07:21

US3242017

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:06
User entered 'I'	System	05 Apr 2021 15:07:21

US3242017

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 20:58:09

US3242017

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
User entered '03 May 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 20:58:09

US3242017

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 20:58:09

US3242017

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:10:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 20:58:09

US3242017

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 20:58:16

US3242017

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:10:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 20:58:16

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:10:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:18
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:10
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	19 Oct 2020 14:56:50

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:10:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:10
User entered '09:38'	Donna Toepfer (b) (4)	19 Oct 2020 14:56:50

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:10:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:18
User entered '19 Oct 2020 09:38'	(b) (4), (b) (6) System	19 Oct 2020 14:56:50

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:10:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:10
User entered 'Safety Call (Safety Call)'	Donna Toepfer (b) (4)	19 Oct 2020 14:56:50

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:10:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:10
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Oct 2020 14:56:50

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User entered 'Day 1 (Day 1)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '17 Oct 2020'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-3 and Temperature for Days 1, 2 & 5. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:58:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:34:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:34:34
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-3 and Temperature for Days 1, 2 & 5. If not collected, please consider recording these as NOT DONE' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	07 Jan 2021 21:34:24
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-3 and Temperature for Days 1, 2 & 5. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Jan 2021 17:34:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
	(b) (4), (b) (6)	
User entered '%'	System	07 Jan 2021 21:34:34
User entered empty.	System	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:34:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:34:34
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:10:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:33

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User entered 'Day 2 (Day 2)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:35:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:35:23
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
	(b) (4), (b) (6)	
User entered '%'	System	07 Jan 2021 21:35:23
User entered empty.	System	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:35:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:35:23
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'Mild (Mild)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:10:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:57:57

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User entered 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:35:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:35:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User entered '%'	(b) (4), (b) (6)	07 Jan 2021 21:35:48
User entered empty.	System	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '98.0' F	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'Moderate (Moderate)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:10:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)'	Donna Toepfer (b) (4)	19 Oct 2020 14:58:25

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User entered 'Day 4 (Day 4)'	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:05:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:05:40
User entered '20 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:05:30
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'I'	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User entered empty.	(b) (4), (b) (6) System	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:10:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:30

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:08:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:08:25
User entered '21 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:05:40
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered '97' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
	(b) (4), (b) (6)	
User entered '%'	System	22 Oct 2020 14:08:25
User entered empty.	System	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	07 Jan 2021 21:36:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	07 Jan 2021 21:36:03
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:10:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:24
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:17
User entered 'None (None)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 14:08:25
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 14:05:40

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:33:45
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:10:53

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:30
User entered '0'	(b) (4), (b) (6) System	22 Oct 2020 17:34:29

US3242017

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:10:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:49:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:34:24
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 17:34:34

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26
	(b) (4)	

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26
	(b) (4)	

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26
	(b) (4)	

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26
	(b) (4)	

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26
	(b) (4)	

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:10:53

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26
	(b) (4)	

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:10:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered 'NA (COVID-19 Negative) (NA)'	Donna Toepfer (b) (4) (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:38:13
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 20:05:26

US3242017

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:34:43
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	28 Oct 2020 13:40:20

US3242017

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:34:43
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 13:40:20

US3242017

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[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 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:34:43
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	28 Oct 2020 13:40:20

US3242017

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User entered 'SICKD1'	(b) (4), (b) (6) System	28 Oct 2020 13:40:20

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '11:52'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User entered '19 Oct 2020 11:52'	(b) (4), (b) (6) System	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '73' in	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11
DataPoint set to visible.	System	28 Oct 2020 13:40:20

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '261' lb	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11
DataPoint set to visible.	System	28 Oct 2020 13:40:20

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '97.2' F	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '64'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User entered 'bpm'	(b) (4), (b) (6) System	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '16'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User entered 'breaths/min'	(b) (4), (b) (6) System	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '130'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User entered 'mmHg'	(b) (4), (b) (6) System	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:06
User entered '82'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User entered 'mmHg'	(b) (4), (b) (6) System	28 Oct 2020 13:42:11

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:49:30

US3242017

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:10:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:49:30

US3242017

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:25

US3242017

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:10:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:12
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Oct 2020 13:42:32
User entered '19 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	28 Oct 2020 13:42:32
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Oct 2020 13:42:25
User entered '28 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:25

US3242017

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:10:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:17
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:44

US3242017

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:10:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:49:30
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:35:17
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 13:42:44

US3242017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:39:58
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:00
	(b) (4)	

US3242017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:39:58
User entered '08 Jan 2021'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:00
	(b) (4)	

US3242017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

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 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:39:58
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:00
	(b) (4)	

US3242017

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

Form: Visit Date

Generated On: 09 Jun 2021 16:10:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	08 Jan 2021 21:08:00

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08 Jan 2021'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[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 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 15:55:21
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:18:27

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 15:55:21
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:18:27

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08 Jan 2021'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:24:28
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:24:28
User entered 'mRNA-1273 (mRNA-1273)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'No (N)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:26
	(b) (4)	

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	08 Jan 2021 21:08:26

US3242017

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

Form: Unblinding

Generated On: 09 Jun 2021 16:10:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered empty.	(b) (4), (b) (6) System	08 Jan 2021 21:08:26

US3242017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:43
	(b) (4)	

US3242017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08 Jan 2021'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:43
	(b) (4)	

US3242017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '14:59'	Erynn McKinley (b) (4)	08 Jan 2021 21:08:43
	(b) (4)	

US3242017

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '08 Jan 2021 14:59'	(b) (4), (b) (6) System	08 Jan 2021 21:08:43

US3242017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Jan 2021 21:09:16
	(b) (4)	

US3242017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '08 Jan 2021'	Erynn McKinley (b) (4)	08 Jan 2021 21:09:16
	(b) (4)	

US3242017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '14:54'	Erynn McKinley (b) (4)	08 Jan 2021 21:09:16
	(b) (4)	

US3242017

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:25:22
User entered '08 Jan 2021 14:54'	(b) (4), (b) (6) System	08 Jan 2021 21:09:16

US3242017

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:10:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:57
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:29
Signature has been broken.	Donna Toepfer (b) (4)	20 Oct 2020 18:40:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 18:40:12
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 14:25:11

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:30:04
User entered	System	21 Oct 2020 18:29:58
'USA-US067-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	21 Oct 2020 18:29:58

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Acute bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:19:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:19:33
Data point term sent to Coder	System	27 Oct 2020 18:18:41
Coding entries removed.	Donna Toepfer (b) (4)	27 Oct 2020 18:18:25
User entered 'Acute Bronchitis' reason for change: Data Entry Error	Donna Toepfer (b) (4)	27 Oct 2020 18:18:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:34:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 17:34:34
Data point term sent to Coder	System	22 Oct 2020 17:33:33
Coding entries removed.	Donna Toepfer (b) (4)	22 Oct 2020 17:33:03
User entered 'Cough' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 17:33:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:43:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:43:44
Data point term sent to Coder	System	20 Oct 2020 18:43:14
User entered 'Possible Covid-19'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	27 Oct 2020 18:18:25
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
User closed query 'PV Query: Please confirm event start date of 17 Oct 2020 as patient was started on azithromycin for acute bronchitis on 16 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:02:37
Query 'PV Query: Please confirm event start date of 17 Oct 2020 as patient was started on azithromycin for acute bronchitis on 16 Oct 2020.' answered with 'updated azithromycin' (Site from Safety).	Donna Toepfer (b) (4)	13 Nov 2020 14:37:15
User opened query 'PV Query: Please confirm event start date of 17 Oct 2020 as patient was started on azithromycin for acute bronchitis on 16 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:27:57
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'PV Query: Please confirm onset date for the event, since mild cough was noted on 17 Oct 2020' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:32
Query 'PV Query: Please confirm onset date for the event, since mild cough was noted on 17 Oct 2020' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:12:00
User entered '17 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	02 Nov 2020 14:10:14
User opened query 'PV Query: Please confirm onset date for the event, since mild cough was noted on 17 Oct 2020' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:18:55
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered empty.	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 14:10:14
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	02 Nov 2020 14:10:14
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 13:51:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:12:09
User entered '27 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	02 Nov 2020 13:51:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:17:55
User entered empty.	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered empty.	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:02:34
Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3.' answered with 'confirm, grade 3 per PI' (Site from Safety).	Donna Toepfer (b) (4)	13 Nov 2020 14:37:35
User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:27:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 17:31:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Oct 2020 20:51:47
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Oct 2020 20:51:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 20:51:21
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 11:50:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'PV Query: Please confirm that the subject was hospitalized over 24 hours. If not please remove hospitalization as seriousness criteria and leave the dates in the narrative.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:36
Query 'PV Query: Please confirm that the subject was hospitalized over 24 hours. If not please remove hospitalization as seriousness criteria and leave the dates in the narrative.' answered with 'confirm, > 24 hrs' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:13:04
User opened query 'PV Query: Please confirm that the subject was hospitalized over 24 hours. If not please remove hospitalization as seriousness criteria and leave the dates in the narrative.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:19:43
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not discharged yet' (Site from System).	Donna Toepfer (b) (4)	20 Oct 2020 20:52:27
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		20 Oct 2020 20:51:47
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).		20 Oct 2020 20:51:47

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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	20 Oct 2020 20:51:47
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 20:51:47
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	20 Oct 2020 20:51:21
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:51:44
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 02:26:30
User entered '19 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 02:26:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '20 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 20:51:21
User entered empty.	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '21 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 17:31:42
User entered empty.	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 20:52:12
User entered empty.	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered empty.	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:39
Query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:13:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	02 Nov 2020 13:51:42
User opened query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:17:40
User entered 'None (NONE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 20:51:21
User entered 'Dose Delayed (DOSE DELAYED)'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

None

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:40:25
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) Donna Toepfer (b) (4)	24 Nov 2020 15:09:22 23 Nov 2020 14:40:26
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 14:40:18
User entered '0' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 14:40:18
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 02:01:57
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there were Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 02:01:31
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there were Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 02:01:23
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '1'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:40:25
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 14:40:18
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 14:40:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered '0'	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:13:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Donna Toepfer (b) (4)	02 Nov 2020 13:51:42
Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:18:16
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	System	20 Oct 2020 18:42:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:42:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	Donna Toepfer (b) (4)	20 Oct 2020 18:42:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	System	20 Oct 2020 18:42:43
Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43
User opened query 'Data is required. Please complete.' (Site from System).		
User entered empty.		

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User entered empty.	Donna Toepfer (b) (4) (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:40:25
User closed query 'Per DM CLR: SAE Narrative = HE IS RECEIVING OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:08:58
Query 'Per DM CLR: SAE Narrative = HE IS RECEIVING OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'error, subject did not receive oxygen per source note' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 14:40:41
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 14:40:18
User entered 'SUBJECT CALLED TO REPORT BEING ADMITTED TO PIEDMONT ATLANTA AROUND 0200 DUE TO WORSENING OF SYMPTOMS. SUBJECT IS HAVING TROUBLE BREATHING AND COUGH HAS WORSENERD. HE IS RECEIVING BREATHING EXERCISES. WE WILL NOT BE ABLE TO COMPLETE SALIVA COLLECTIONS OR SYMPTOM LOG WHILE HE IS IN THE HOSPITAL. MEDICAL RECORDS WILL BE REQUESTED' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 14:40:18
User opened query 'Per DM CLR: SAE Narrative = HE IS RECEIVING OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 02:02:09
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:02:28

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Narrative](#)

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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	13 Nov 2020 14:39:51
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:26:49
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:36
User closed query 'PV Query: Since the subject was confirmed negative for COVID, please remove symptom log for for COVID-19 from the EDC.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:45
User closed query 'PV Query: Was additional treatment given for the event including medical intervention and/or surgical treatments? Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 12:57:43
Query 'PV Query: Since the subject was confirmed negative for COVID, please remove symptom log for for COVID-19 from the EDC.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:13:35
Query 'PV Query: Was additional treatment given for the event including medical intervention and/or surgical treatments? Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	02 Nov 2020 14:13:26
User opened query 'PV Query: Since the subject was confirmed negative for COVID, please remove symptom log for for COVID-19 from the EDC.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:20:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

1831 of 2184

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was additional treatment given for the event including medical intervention and/or surgical treatments? Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:18:39
User entered 'Subject called to report being admitted to Piedmont Atlanta around 0200 due to worsening of symptoms. Subject is having trouble breathing and cough has worsened. He is receiving breathing exercises and oxygen. We will not be able to complete saliva collections or symptom log while he is in the hospital. Medical records will be requested' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Oct 2020 20:51:21
User entered empty.	Donna Toepfer (b) (4)	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 20:51:21
User entered '0'	System	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 18:18:25
User entered '0'	System	20 Oct 2020 18:42:43

US3242017

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:10:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 20:52:12

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:10:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:57
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:23
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 15:04:22

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 15:07:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 15:07:12
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 15:05:52
User entered 'Tamsulosin'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Benign Prostatic Hyperplasia'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User closed query 'Per DM CLR: Please review the dose of this medication 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)	24 Oct 2020 14:46:07
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	16 Sep 2020 15:54:32
Signature has been broken.	Donna Toepfer (b) (4)	16 Sep 2020 15:54:20
User entered '0.4' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 15:54:20
User opened query 'Per DM CLR: Please review the dose of this medication 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)	16 Sep 2020 04:44:01
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '4'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'mg (mg)'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 03:28:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	07 Aug 2020 15:05:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 15:05:38
User entered 'UN UNK 2019'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 15:05:38

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	09 Nov 2020 19:39:40 09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Sep 2020 12:58:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 15:07:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 15:07:14
Data point term sent to Coder User entered 'Atenolol'	System Donna Toepfer (b) (4)	07 Aug 2020 15:06:53 07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Hypertension'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '25'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'mg (mg)'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 14:46:44
User entered 'UN UNK 2015' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 16:53:15
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	16 Sep 2020 15:57:18
Signature has been broken.	Donna Toepfer (b) (4)	16 Sep 2020 15:57:09
User entered 'UN UNK 2019' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 15:57:09
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:52:07
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 03:28:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	07 Aug 2020 15:07:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

1865 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). User entered 'UN UNK 2015'	System	07 Aug 2020 15:06:52
	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 15:06:52

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:38
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	09 Nov 2020 19:39:41 09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 15:09:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 15:09:16
Data point term sent to Coder User entered 'Triamterene/Hydrochlorothiazide'	System Donna Toepfer (b) (4)	07 Aug 2020 15:08:54 07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Hypertension'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '37.5/25'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'mg (mg)'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 14:47:10
User entered 'UN UNK 2015' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 17:07:41
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	16 Sep 2020 16:00:27
Signature has been broken.	Donna Toepfer (b) (4)	16 Sep 2020 15:58:41
User entered 'UN UNK 2019' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 15:58:41
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 04:52:36
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 03:28:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	07 Aug 2020 15:08:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

1884 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). User entered 'UN UNK 2015'	System	07 Aug 2020 15:07:56
	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 15:07:56

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	09 Nov 2020 19:39:41 09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:38:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 14:38:46
Data point term sent to Coder User entered 'Acetaminophen'	System Grace Newville (b) (4) (b) (4)	09 Sep 2020 14:37:24 09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Injection site pain'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '650'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'mg (mg)'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'once (ONCE)'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'Oral (ORAL)'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered empty.	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '0'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered '8 Sep 2020'	Grace Newville (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.	(b) (4), (b) (6)	13 Nov 2020 15:10:58
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.	Donna Toepfer (b) (4)	05 Oct 2020 13:12:02
' answered with 'did not meet the AE reporting criteria' (Site from DM).		

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	05 Oct 2020 10:04:05
	Nathan Segall (b) (4) [REDACTED]	10 Sep 2020 12:58:09
User entered 'Yes (Y)'	Grace Newville (b) (4) (b) (4)	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
User entered empty.	System	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
User entered empty.	System	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:43
User entered empty.	System	09 Sep 2020 14:37:20

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:55:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:55:37
Data point term sent to Coder	System	09 Nov 2020 19:39:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:16:16
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 Oct 2020 21:16:16
Data point term sent to Coder	System	28 Oct 2020 23:03:34
User entered 'Albuterol'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Acute Bronchitis'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '90'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'ug (ug)'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '0'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '26 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User entered empty.	System	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User entered empty.	System	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:31:48
User entered empty.	System	28 Oct 2020 23:02:46

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 19:40:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 19:40:38
Data point term sent to Coder DataPoint Verified.	System	09 Nov 2020 19:39:41
	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:12:23
Data point term sent to Coder	System	28 Oct 2020 23:05:35
User entered 'Benzonatate'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Acute Bronchitis'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '200'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'mg (mg)'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'three times daily (TID)'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '0'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '27 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User entered '3'	System	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User entered '1'	System	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:21
User entered '804 (804)'	System	28 Oct 2020 23:05:03

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User closed query 'According to Hospital Summary the subject completed on 21OCT2020 three days of 500 mg Azithromycin (one as OP and 2 days IV). Refer to Piedmont Healthcare Records - Page 5.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 14:59:49
Query 'According to Hospital Summary the subject completed on 21OCT2020 three days of 500 mg Azithromycin (one as OP and 2 days IV). Refer to Piedmont Healthcare Records - Page 5.' answered with 'updated in source note' (Site from CRA).	Donna Toepfer (b) (4)	19 Feb 2021 14:23:05
User opened query 'According to Hospital Summary the subject completed on 21OCT2020 three days of 500 mg Azithromycin (one as OP and 2 days IV). Refer to Piedmont Healthcare Records - Page 5.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:04:24
User closed query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:04:24
Query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated' answered with '500mg not found in med records on those dates. please advise' (Site from CRA).	Donna Toepfer (b) (4)	18 Feb 2021 14:04:31
User opened query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 15:27:53
User closed query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated. ?' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 15:27:53
Query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated. ?' answered with 'hospital meds not added to edc' (Site from CRA).	Donna Toepfer (b) (4)	10 Feb 2021 15:42:37

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
User opened query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated. ?' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:05:32
User closed query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:03:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
Query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated.' answered with 'hospital meds not added to EDC' (Site from CRA).	Donna Toepfer (b) (4)	30 Jan 2021 15:06:37
User opened query 'According to hospital records patient was given Azithromycin (500 mg) beginning 19OCT2020. Please refer to source and add medication as indicated.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:55:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 05:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 05:24:43
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:34:15
Data point term sent to Coder	System	19 Nov 2020 21:52:43
DataPoint Un-verified.	Erynn McKinley (b) (4)	19 Nov 2020 21:52:18
Coding entries removed.	Erynn McKinley (b) (4)	19 Nov 2020 21:52:18
User entered 'ZITHROMAX Z - Pak' reason for change: Data Entry Error	Erynn McKinley (b) (4)	19 Nov 2020 21:52:18

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:40:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	09 Nov 2020 19:39:41 09 Nov 2020 19:39:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:59:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:59:13
Data point term sent to Coder User entered 'Zithromax'	System Donna Toepfer (b) (4)	28 Oct 2020 23:07:44 28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Acute Bronchitis'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '250'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'mg (mg)'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'other (OTHER)'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'As directed'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:34
DataPoint Un-verified.	Donna Toepfer (b) (4)	13 Nov 2020 14:36:41
User entered '18 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Nov 2020 14:36:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '16 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '0'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:34
DataPoint Un-verified.	Donna Toepfer (b) (4)	13 Nov 2020 14:36:41
User entered '20 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Nov 2020 14:36:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User entered empty.	System	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User entered empty.	System	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:34
User entered empty.	System	28 Oct 2020 23:07:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROMFED DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 19:40:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 19:40:39
Data point term sent to Coder	System	09 Nov 2020 19:39:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROMFED DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:16:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:16:34
Data point term sent to Coder	System	28 Oct 2020 23:12:50
User entered 'Bromfed DM(brompheniramine/dextromethorphan/pseudoephedrine)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

PRODUCTION RELEASE (v12.003
EAB) (1725)

1968 of 2184

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Acute Bronchitis'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '2/10/30'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'mg/per 5 ml'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '18 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '0'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '20 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User entered empty.	System	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User entered empty.	System	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:32:47
User entered empty.	System	28 Oct 2020 23:12:34

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User closed query 'On page 16 of Med Records this med is listed as given in ED although there is no time range of administration..' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 15:02:12
Query 'On page 16 of Med Records this med is listed as given in ED although there is no time range of administration..' answered with 'entered per source documentation' (Site from CRA).	Donna Toepfer (b) (4)	19 Feb 2021 14:24:45
User opened query 'On page 16 of Med Records this med is listed as given in ED although there is no time range of administration..' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:24:04
User closed query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated. ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:24:04
Query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated. ' answered with 'Those meds specifically say "has no administration in time range". These were not administered.' (Site from CRA).	Susan Jones (b) (4) (b) (4)	17 Feb 2021 23:22:09
User opened query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated. ' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 15:30:06
User closed query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated. ?' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 15:30:06
Query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated. ?' answered with 'hospital meds not added to source' (Site from CRA).	Donna Toepfer (b) (4)	10 Feb 2021 15:43:14

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

Name of Medication

Audit	User	Time (GMT)
User opened query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated. ?' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:22:17
User closed query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:22:17
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
Query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated.' answered with 'hospital meds not added to EDC' (Site from CRA).	Donna Toepfer (b) (4)	30 Jan 2021 15:07:00
User opened query 'According to Hospital Medical Records the subject was given Enoxaparin (30mg) and Guaifenesin (100 mg) on 19OCT2020. Please refer to source and add medications as indicated.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 14:51:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE;PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 19:55:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 19:55:35
Data point term sent to Coder	System	09 Nov 2020 19:39:41
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE;PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:04:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:04:44
Data point term sent to Coder	System	28 Oct 2020 23:14:52
User entered 'Promethazine/Codeine'	Donna Toepfer (b) (4) (b) (4) (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Acute Bronchitis'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '6.25/10'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Mg per 5 ml'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered empty.	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '21 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '0'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered '27 Oct 2020'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:39:40
User entered 'No (N)'	Donna Toepfer (b) (4)	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User entered '2'	System	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User entered '1'	System	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:08
User entered '804 (804)'	System	28 Oct 2020 23:14:36

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 13:18:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 13:18:46
Data point term sent to Coder	System	12 Feb 2021 13:18:05
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'Bronchitis'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered '650'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'mg (mg)'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered empty.	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered '0'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered '21 Oct 2020'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	12 Feb 2021 18:13:59
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User entered empty.	(b) (4), (b) (6) System	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User entered empty.	(b) (4), (b) (6) System	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:14
User entered empty.	(b) (4), (b) (6) System	12 Feb 2021 13:18:00

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 21:12:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 21:12:56
Data point term sent to Coder	System	18 Feb 2021 19:30:13
User entered 'Azithromycin'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'Acute Bronchitis'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered '500'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'once daily (QD)'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered '19 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered '20 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:25
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 19:30:02
	(b) (4)	

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User entered '1'	(b) (4), (b) (6) System	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User entered '1'	(b) (4), (b) (6) System	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:10:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 16:33:18
User entered '804 (804)'	(b) (4), (b) (6) System	18 Feb 2021 19:30:02

US3242017

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:10:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:40:29
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Sep 2020 12:58:09
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 16:12:21

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
User entered '21/Oct/2020 18:31'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:10:53

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
User entered '23/Oct/2020 12:20'	System	23 Oct 2020 12:20:36

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:10:53

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 12:20:36

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
User entered '28/Oct/2020 09:04'	System	28 Oct 2020 13:04:53

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:10:53

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 12:57:52
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 13:04:53

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
User entered '03/Nov/2020 07:57'	System	03 Nov 2020 12:58:01

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:10:53

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:05:00
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 12:58:01

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:32:44
User entered '16/Nov/2020 17:05'	System	16 Nov 2020 17:05:17

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:10:53

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:32:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 15:14:35
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 17:05:17

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:32:44
User entered '17/Nov/2020 10:14'	System	17 Nov 2020 15:14:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:10:53

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.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:34:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 11:32:44
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 15:14:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'USA-US067-2020-MRNA-1273-P301000007'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'Yes (Y)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:31:38
User entered 'No (N)'	System	21 Oct 2020 18:29:58

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:15:24
User closed query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:06
Query 'Please enter Investigator's first name.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:01
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Jon' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:56
User opened query 'Please enter Investigator's first name.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:34:45
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Nathan'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:26
Query 'Please enter Investigator's last name' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:19
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Finley' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Investigator's last name' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:34:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Segall'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User entered '175 COUNTRY CLUB DRIVE 100A' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:28:56
Query 'Please enter street of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:28:34
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '175 Country Club Drive' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter street of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:01
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '175 Country Club Drive St100A'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:37
Query 'Please enter city of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:11
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'Stockbridge' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter city of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:38:03
Query 'Please enter state of site address' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:45
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:29
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:03
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'Stockbridge'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:15:51
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:31
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered 'GA' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:37:31
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:37:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:36:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:05
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered 'GA'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:16:05
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 13:29:49
Un-reviewed for Safety.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
Signature has been broken.	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Apr 2021 13:27:37
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 03:35:08
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 13:04:45
Un-reviewed for Safety.	System	23 Oct 2020 12:20:36
User entered empty.	System	23 Oct 2020 12:20:36
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 12:20:24
User entered '30281'	Donna Toepfer (b) (4)	22 Oct 2020 17:32:12

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 18:05:20
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:36:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:32:02
User entered 'US'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 16:10:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
	(b) (4)	
User entered '7'	System	24 Nov 2020 19:34:37
User entered '6'	System	17 Nov 2020 15:14:57
User entered '5'	System	16 Nov 2020 17:05:17
User entered '4'	System	03 Nov 2020 12:58:01
User entered '3'	System	28 Oct 2020 13:04:53
User entered '2'	System	23 Oct 2020 12:20:36
User entered '1'	System	21 Oct 2020 18:31:57

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:10:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:16:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered '24/Nov/2020 19:34'	System	24 Nov 2020 19:34:37

US3242017

Folder: SAE USA-US067-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:10:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:16:18
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 18:05:20
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 19:34:37