

US3242051 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:11:53

All time stamps listed in this document are displayed in GMT

US3242051

Form: Participant Creation

Data signed: (b) (4) 08 Feb 2021 20:09:39

Generated On: 09 Jun 2021 16:11:53

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Participant ID

US3242051

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

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US3242051

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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

Visit date (dd MMM yyyy)	08 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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US3242051

Folder: Screening

Form: Demographics

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 08 Feb 2021 20:09:41

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	8 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 08 Feb 2021 20:09:41

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Feb 2021 20:10:11

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Feb 2021 20:09:41

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Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Feb 2021 20:09:41

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 20:10:11

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 15:09
Height (xxx.x)	74 in
Weight (xxx.x)	210 lb
BMI (xxx.x)	27.01878 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 20:10:11

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Feb 2021 20:10:11

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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**

IT MANAGER, OFFICE  
INTERACTION

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Feb 2021 20:10:11

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:10:11

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

Visit date (dd MMM yyyy)	8 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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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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

What was the participant's randomization number? 102409

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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)	8 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 15:09
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 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)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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)	8 AUG 2020
Time of assessment (00:00-23:59)	16:19 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 16:19
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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.*

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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) 08 AUG 2020

What was the treatment time? (00:00-23:59) 15:49 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 15:49

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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

Collection date (dd MMM yyyy)	8 AUG 2020
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Collection time (00:00-23:59)	15:42 (24 HR)
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Collection date and time (derived)	8 AUG 2020 15:42
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US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)			8 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	8 AUG 2020 15:30
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 16:22

PC Open Date & Time

08 AUG 2020 16:09

PC Close Date & Time

08 AUG 2020 18:39

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**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 98.3 °F

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

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

PC Time Stamp	08 AUG 2020 20:17
PC Open Date & Time	08 AUG 2020 19:34
PC Close Date & Time	09 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**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

98.4 °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

09 AUG 2020 15:45

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**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

97.9 °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):

PC Time Stamp

10 AUG 2020 14:08

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**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

97.9 °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):

PC Time Stamp

11 AUG 2020 17:38

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**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

12 AUG 2020 20:35

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 16:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59



US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**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

98.0 °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

14 AUG 2020 14:19

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

10

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

08 AUG 2020 16:19

PC Open Date & Time

08 AUG 2020 16:09

PC Close Date & Time

08 AUG 2020 18:39

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**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

08 AUG 2020 20:18

PC Open Date & Time

08 AUG 2020 19:34

PC Close Date & Time

09 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**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

09 AUG 2020 15:44

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**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

10 AUG 2020 14:08

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**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 17:36

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**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 AUG 2020 20:36

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**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 AUG 2020 16:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59



US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**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

14 AUG 2020 14:19

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**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 ☐

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 16:20
PC Open Date & Time	08 AUG 2020 16:09
PC Close Date & Time	08 AUG 2020 18:39

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**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 ☐

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 20:19
PC Open Date & Time	08 AUG 2020 19:34
PC Close Date & Time	09 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**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 ☒

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 15:43
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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 ☒



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 14:09
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**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 ☒

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EAB) (1725)

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 17:36
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**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 ☒

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:36
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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 ☒

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 16:09
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**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 ☒



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

US3242051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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

Visit date (dd MMM yyyy)	11 SEP 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	VISIT2
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US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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)	11 SEP 2020
Time of assessment (00:00-23:59)	16:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:58
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3242051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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.*

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 16:28 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:28

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

US3242051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 11 SEP 2020

Collection time (00:00-23:59) 16:10 (24 HR)

Collection date and time (derived) 11 SEP 2020 16:10

US3242051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:00	11 SEP 2020 16:00
Nasopharyngeal Swab 2	No		

US3242051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 17:00

PC Open Date & Time

11 SEP 2020 16:48

PC Close Date & Time

11 SEP 2020 19:18



US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**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 98.0 °F

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

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

PC Time Stamp	11 SEP 2020 20:15
PC Open Date & Time	11 SEP 2020 20:13
PC Close Date & Time	12 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 19:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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 SEP 2020 18:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:19

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 09:30

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**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

98.4 °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

17 SEP 2020 17:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**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

11 SEP 2020 17:01

PC Open Date & Time

11 SEP 2020 16:48

PC Close Date & Time

11 SEP 2020 19:18



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**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

11 SEP 2020 20:16

PC Open Date & Time

11 SEP 2020 20:13

PC Close Date & Time

12 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**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

12 SEP 2020 19:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**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

13 SEP 2020 18:08

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**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

14 SEP 2020 18:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**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

15 SEP 2020 21:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**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

17 SEP 2020 09:30

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**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

17 SEP 2020 17:52

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**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 ☐



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:01
PC Open Date & Time	11 SEP 2020 16:48
PC Close Date & Time	11 SEP 2020 19:18

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**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 ☐

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:16
PC Open Date & Time	11 SEP 2020 20:13
PC Close Date & Time	12 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**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 ☒

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:41
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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 ☒

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EAB) (1725)

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:09
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**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 ☒



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:07
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**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 ☒

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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 ☒

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EAB) (1725)

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 09:31
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:52
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3242051

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*



US3242051

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 14:46
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 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)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

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.*



US3242051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	15:16 (24 HR)
Collection date and time (derived)	9 OCT 2020 15:16

US3242051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:10:11

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

<b>TIMEPOINT</b>	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	09 OCT 2020 15:18:53
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

15 OCT 2020 14:51:20

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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	24 OCT 2020 12:32:16
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 NOV 2020 14:05:20
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☒

Yes ☐

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

15 NOV 2020 16:28:49

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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



**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 17:03:11
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

24 NOV 2020 14:04:05

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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	01 DEC 2020 08:15:47
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 14:33:07

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☒

Yes ☐

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

15 DEC 2020 09:16:24

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 15:28:20

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

28 DEC 2020 18:14:43

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 09:56:59

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 12:11:49

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

<b>TIMEPOINT</b>	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	19 JAN 2021 09:34:12
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

25 JAN 2021 17:26:50

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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	01 FEB 2021 07:58:27
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

<b>TIMEPOINT</b>	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 <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 FEB 2021 10:35:49
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 09:17:21
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

24 FEB 2021 16:24:59

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

01 MAR 2021 12:26:19

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

08 MAR 2021 07:26:43

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

<b>TIMEPOINT</b>	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 12:02:17
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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	25 MAR 2021 17:59:21
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	30 MAR 2021 15:28:33
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 07:42:17

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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

14 APR 2021 09:16:44

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 11:12:07

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 08:42:01

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☒

Yes ☐

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

03 MAY 2021 18:04:28

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 MAY 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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

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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUN 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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28 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JUL 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUL 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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

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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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16 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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23 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 AUG 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 SEP 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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20 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 SEP 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 OCT 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 OCT 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2021 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 DEC 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐ Yes ☐

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

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2021 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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

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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JAN 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐ Yes ☐

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

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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

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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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28 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAR 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 APR 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 APR 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 APR 2022 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐ Yes ☐

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

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUN 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUN 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2022 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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11 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUL 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2022 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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="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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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°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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 <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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59



US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 SEP 2022 23:59

US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**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 ☐

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

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US3242051

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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"/>

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2022 23:59



US3242051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:11:53

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
Yes	No	01 MAR 2021 12:26:38

US3242051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3242051

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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

Visit date (dd MMM yyyy)	16 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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US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:40:26

Generated On: 09 Jun 2021 16:11:53

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) \_\_\_\_\_

US3242051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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.*

US3242051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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

Collection date (dd MMM yyyy)	16 MAR 2021
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Collection time (00:00-23:59)	16:10 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 MAR 2021 16:10
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US3242051

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:54:58

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:54:58

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3242051**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

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*

**US3242051**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242051

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:53

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

**US3242051**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:11:53**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3242051

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

Form: Visit Date

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 20 JAN 2021

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

Folder OID UNBLND\_DECIDE

US3242051

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 15:56:44

Generated On: 09 Jun 2021 16:11:53

Date of updated informed consent ( <i>dd MMM yyyy</i> )	20 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	20 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3242051

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

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

US3242051

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	17:55 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 17:55
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG



US3242051

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	18:47 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 18:47
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3242051

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

Form: Physical Examination

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

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.*

US3242051

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

Form: Exposure

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 20 JAN 2021

What was the treatment time? (00:00-23:59) 18:17 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 18:17

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

What was the frequency of the study treatment dosing? ONCE

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

US3242051

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

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

Collection date (dd MMM yyyy)	20 JAN 2021
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Collection time (00:00-23:59)	17:33 (24 HR)
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Collection date and time (derived)	20 JAN 2021 17:33
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US3242051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 20 JAN 2021

Collection time (00:00 - 23:59) 15:57

Collection Date and Time (derived) 20 JAN 2021 15:57

US3242051

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

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Feb 2021 20:09:41

Generated On: 09 Jun 2021 16:11:53

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



US3242051

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 17:19:36

Generated On: 09 Jun 2021 16:11:53

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

Visit date (dd MMM yyyy)	16 FEB 2021
--------------------------	-------------

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

Folder OID	OLD29
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US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 17:19:36

Generated On: 09 Jun 2021 16:11:53

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)	16 FEB 2021
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 15:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 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)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 17:19:36

Generated On: 09 Jun 2021 16:11:53

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)	16 FEB 2021
Time of assessment (00:00-23:59)	17:03 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 17:03
Temperature (xxx.x)	97.6 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3242051

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 17:19:36

Generated On: 09 Jun 2021 16:11:53

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.*

US3242051

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 17:19:36

Generated On: 09 Jun 2021 16:11:53

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 16:29 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 16:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3242051

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 17:19:36

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:01:43

Generated On: 09 Jun 2021 16:11:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3242051

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:01:43

Generated On: 09 Jun 2021 16:11:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3242051

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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

Visit date (dd MMM yyyy)	16 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	OLD57
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US3242051

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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) \_\_\_\_\_

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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.*

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 12:24:32

Generated On: 09 Jun 2021 16:11:53

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

Collection date (dd MMM yyyy)	16 MAR 2021
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Collection time (00:00-23:59)	16:10 (24 HR)
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Collection date and time (derived)	16 MAR 2021 16:10
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US3242051

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Feb 2021 20:09:39

Generated On: 09 Jun 2021 16:11:53

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3242051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:11:53

AEID

Adverse event

ACUTE OTITIS MEDIA, RIGHT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3242051

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:11:53

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

US3242051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:11:53

AEID	USA-US067-2020-MRNA-1273-P30 1000011
Adverse event	TRIMALLEOLAR ANKLE FRACTURE, RIGHT
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)	1 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	5 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:11:53

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3242051

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 13:01:18

Generated On: 09 Jun 2021 16:11:53

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DURING SAFETY CALL,  
SUBJECT REPORTED HE BROKE  
HIS RIGHT ANKLE(SUBJECT  
STATED HE "ROLLED" HIS  
ANKLE) ON 01NOV2020 AND  
WAS ADMITTED TO GRADY  
MEMORIAL ON 02NOV2020.  
HAD SURGERY TO REPAIR ON  
03NOV2020 AND WAS  
RELEASED ON 05NOV2020.  
COVID TEST IN HOSPITAL WAS  
NEGATIVE. RECORDS HAVE  
BEEN REQUESTED.  
RECORDS, RECEIVED,  
DIAGNOSIS AND DATES  
UPDATED.  
UPDATE 1/6/21: REVIEW OF  
XRAYs POST ORTHOPEDIC  
APPT, STATES ANKLE IS  
HEALING, SUBJECT IS STILL IN  
A BOOT FOR PART OF THE DAY  
AND CONTINUES PHYSICAL  
THERAPY.

---

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)	

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US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

---

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

Yes ☒

No ☐

---

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

---

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication TRAZODONE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE OTITIS MEDIA, RIGHT

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE OTITIS MEDIA, RIGHT

Dose per administration 875

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication	OFLOXACIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACUTE OTITIS MEDIA, RIGHT
Dose per administration	0.3
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	% PERCENT
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	FIVE TIMES DAILY
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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 checked="" type="radio"/>
If route of administration is Other, specify		OTIC
Start date (dd MMM yyyy)	22 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		2 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE, RIGHT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication ASPIRIN EC

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE, RIGHT

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication BISACODYL

Prophylaxis Yes ☒  
No ☐

Indication CONSTIPATION AFTER SURGERY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE, RIGHT

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication OXYCODONE IR

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE, RIGHT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication MOBIC

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE, RIGHT

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication JUVEDERM

Prophylaxis Yes ☐  
No ☒

Indication COSMETIC

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2016		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE/NAUSEA

Dose per administration 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication LACTATED RINGER BOLUS

Prophylaxis Yes ☒  
No ☐

Indication TRIMALLEOLAR ANKLE  
FRACTURE(PROPHYLAXIS)

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication NACL

Prophylaxis Yes ☒  
No ☐

Indication TRIMALLEOLAR ANKLE  
FRACTURE, PROPHYLAXIS

Dose per administration 0.9

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

If dose unit is Other, specify PERCENT

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication TRIMALLEOLAR ANKLE  
FRACTURE, RIGHT

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 21:17:41

Generated On: 09 Jun 2021 16:11:53

	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 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)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Feb 2021 20:09:40

Generated On: 09 Jun 2021 16:11:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 20 Apr 2021 21:17:42

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 NOV 2020	ANKLE REPAIR, RIGHT(SMALL FRAGMENT PLATE AND SCREWS)	Adverse Event	
02 NOV 2020	XRAY, RIGHT ANKLE	Adverse Event	
02 NOV 2020	COMPUTERIZED TOMOGRAPHY	Adverse Event	
02 NOV 2020	EKG	Adverse Event	
02 NOV 2020	SPLINT, RIGHT ANKLE (PRE-SURGERY)	Adverse Event	
03 NOV 2020	SPLINT, RIGHT ANKLE (POST SURGERY_	Adverse Event	
02 NOV 2020	SUTURES	Adverse Event	

US3242051

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:11:53

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



US3242051

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:11:53

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:53
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.	True

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/NOV/2020 10:40
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

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 20:38
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

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/DEC/2020 07:39
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

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/JAN/2021 21:15
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

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 01:17:39

Generated On: 09 Jun 2021 16:11:53

SAEID	USA-US067-2020-MRNA-1273-P301000011
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
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30248
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	13/APR/2021 13:05
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



Audit

US3242051 (Prod: Clinical Research Atlanta - ERN-PPDS)

**US3242051**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:11:53**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:35
User entered 'US3242051'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 19:05:32

US3242051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:19:37

US3242051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:51
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Aug 2020 19:05:33

US3242051

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:14:51
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	08 Aug 2020 19:19:37

**US3242051**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'SCRN'	(b) (4), (b) (6)	08 Aug 2020 19:19:37
	System	

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Aug 2020 19:05:34

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '54'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01



**US3242051**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:11:53**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'YEARS'	(b) (4), (b) (6)	08 Aug 2020 19:20:01
	System	

**US3242051**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:11:53**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered '54'	(b) (4), (b) (6)	08 Aug 2020 19:20:26
	System	

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered 'Male (M)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered 'I'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01



US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:53

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:15:03
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:01

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:26

**US3242051**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered 'Aug 2020'	(b) (4), (b) (6) System	08 Aug 2020 19:20:26

**US3242051**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered '2020'	(b) (4), (b) (6) System	08 Aug 2020 19:20:26



US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered 'Amendment 1 (1)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:26

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:26

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:20:26

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:20:26

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:26

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:44
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Aug 2020 19:05:33

US3242051

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered '1'	(b) (4), (b) (6)	08 Aug 2020 19:20:30
	System	

US3242051

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:50
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:30



US3242051

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:11:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:16:55
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:39

US3242051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:21:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:21:42
Data point term sent to Coder	System	08 Aug 2020 19:20:56
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:54

US3242051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'UN UNK 2006'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:54

US3242051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:54

US3242051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:54

US3242051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:20:54

US3242051

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:20:54

**US3242051**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'Jan 2006'	(b) (4), (b) (6)	08 Aug 2020 19:20:54
	System	



**US3242051**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered '2006'	(b) (4), (b) (6) System	08 Aug 2020 19:20:54

**US3242051**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered empty.	(b) (4), (b) (6) System	08 Aug 2020 19:20:54

**US3242051**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered empty.	(b) (4), (b) (6) System	08 Aug 2020 19:20:54

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:22:42
Data point term sent to Coder	System	08 Aug 2020 19:21:57
User entered 'Insomnia'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'UN UNK 2015'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:21:04



US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'Jan 2015'	(b) (4), (b) (6)	08 Aug 2020 19:21:04
	System	

**US3242051**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered '2015'	(b) (4), (b) (6) System	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 19:21:04
	System	

**US3242051**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered empty.	(b) (4), (b) (6) System	08 Aug 2020 19:21:04

US3242051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 19:22:42
Data point term sent to Coder	System	08 Aug 2020 19:21:59
User entered 'Anxiety'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:12

US3242051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'UN UNK 2005'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:12

US3242051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:12



**US3242051**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:11:53**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:12

US3242051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:21:12

US3242051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:12

**US3242051**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered 'Jan 2005'	(b) (4), (b) (6) System	08 Aug 2020 19:21:12

**US3242051**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered '2005'	(b) (4), (b) (6) System	08 Aug 2020 19:21:12

US3242051

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered empty.	(b) (4), (b) (6) System	08 Aug 2020 19:21:12

**US3242051**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered empty.	(b) (4), (b) (6) System	08 Aug 2020 19:21:12

US3242051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:36:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:36:20
Data point term sent to Coder	System	08 Aug 2020 19:21:57
User entered 'Drug allergy-Codeine'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:32



US3242051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'UN UNK 2000'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:32

US3242051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:32

US3242051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:32

US3242051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:21:32

US3242051

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:17:09
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:21:32

**US3242051**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'Jan 2000'	(b) (4), (b) (6)	08 Aug 2020 19:21:32
	System	

**US3242051**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered '2000'	(b) (4), (b) (6) System	08 Aug 2020 19:21:32

**US3242051**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 19:21:32
	System	



**US3242051**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 19:21:32
	System	

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered '15:09'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered '8 Aug 2020 15:09'	(b) (4), (b) (6)	
	System	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered '74' in	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31
DataPoint set to visible.	System	08 Aug 2020 19:20:30

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered '210' lb	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31
DataPoint set to visible.	System	08 Aug 2020 19:20:30

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
Amendment Manager: User entered '27.01878'	System	16 Sep 2020 23:49:03
User entered '27.0'	System	08 Aug 2020 19:22:31
DataPoint set to visible.	System	08 Aug 2020 19:20:30



US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'kg/m2'	(b) (4), (b) (6)	08 Aug 2020 19:22:31
DataPoint set to visible.	System	08 Aug 2020 19:20:30
	System	

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:27:11
Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	15 Sep 2020 17:16:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 17:16:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:19:41
User entered '98.4' F	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 17:16:34
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:27:24
Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	15 Sep 2020 17:17:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 17:16:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:19:49
User entered '70'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'bpm'	(b) (4), (b) (6)	08 Aug 2020 19:22:31
	System	

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:27:39
Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	15 Sep 2020 17:17:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 17:16:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to VID1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:19:59
User entered '16'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Aug 2020 19:22:31



US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:27:52
Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	15 Sep 2020 17:17:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 17:16:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:20:07
User entered '130'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'mmHg'	(b) (4), (b) (6)	08 Aug 2020 19:22:31
	System	

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:28:17
Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	15 Sep 2020 17:17:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 17:16:34
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:20:15
User entered '90'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:31

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:51:59
	(b) (4), (b) (6)	
User entered 'mmHg'	(b) (4), (b) (6)	08 Aug 2020 19:22:31
	System	

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59

US3242051

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59

US3242051

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:39

US3242051

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:19
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 15:20:00
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 20:22:43
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 19:22:39



US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

[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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37



US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'IT Manager, office interaction'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

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**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

**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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

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) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'I'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '0'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 12:51:59
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 19:23:37

US3242051

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:39
User entered 'Yes (Y)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	08 Aug 2020 19:23:52

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:39
User entered '8 Aug 2020'	(b) (4), (b) (6) Donna Toepfer (b) (4)	08 Aug 2020 19:23:52

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:39
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	08 Aug 2020 19:23:52



**US3242051**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'VISIT1'	System	08 Aug 2020 19:23:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered '08 AUG 2020'	RWS_ENDPOINT	08 Aug 2020 19:45:24
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:08:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:08:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 19:45:24
User entered '102409' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Aug 2020 19:45:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT	08 Aug 2020 19:45:24
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:24:04

US3242051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:24:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:24:04

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:11:53**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:24:04



US3242051

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:24:04

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:44:15
Query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	02 Sep 2020 13:56:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	02 Sep 2020 13:55:57
User opened query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:10
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 clarif' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:10
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 clarif' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:21:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:21:47
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 clarif' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:24:09
User entered '74' in	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	02 Sep 2020 13:55:57
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 clarif' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:17
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 clarif' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:21:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:21:47
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 clarif' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:24:14
User entered '210' lb	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:44:15
Query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	02 Sep 2020 13:56:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	02 Sep 2020 13:55:57
User opened query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:10
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 clarif' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:10
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 clarif' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:21:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:21:47
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 clarif' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:24:09
User entered '74' in	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	02 Sep 2020 13:55:57
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 clarif' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:17
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 clarif' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:21:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:21:47
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 clarif' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:24:14
User entered '210' lb	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '15:09'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '8 Aug 2020 15:09'	(b) (4), (b) (6)	08 Aug 2020 20:16:58
	System	

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:17:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:17:12
User entered '98.4' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:17:12
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '70'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'bpm'	(b) (4), (b) (6) System	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '16'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '130'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '90'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

US3242051

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:44:15
Query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	02 Sep 2020 13:56:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	02 Sep 2020 13:55:57
User opened query 'Per CDM RQ: Previous response noted.Please remove the units "in,lb"recorded in Height and weight data fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:10
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 clarif' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:10
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 clarif' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:21:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:21:47
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 clarif' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:24:09
User entered '74' in	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	02 Sep 2020 13:55:57
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 clarif' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:03:17
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 clarif' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 17:21:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 17:21:47
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 clarif' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:24:14
User entered '210' lb	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
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 08:32:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'value correct per protocol' (Site from System).	Donna Toepfer (b) (4)	08 Aug 2020 20:25:50
User opened 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).		08 Aug 2020 20:25:44
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:25:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:25:44
User entered '16:19' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:25:44
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User entered '8 Aug 2020 16:19'	System	08 Aug 2020 20:25:44
User entered empty.	System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:25:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:25:44
User entered '98.0' F reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:25:44
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:25:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:25:44
User entered '80' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:25:44
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User entered 'bpm'	System	08 Aug 2020 20:25:44
User entered empty.	System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:25:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:25:44
User entered '18' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:25:44
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	08 Aug 2020 20:25:44
User entered empty.	System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:25:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:25:44
User entered '130' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:25:44
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User entered 'mmHg'	System	08 Aug 2020 20:25:44
User entered empty.	System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:11
	(b) (4), (b) (6)	
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:25:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Aug 2020 20:25:44
User entered '88' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:25:44
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Aug 2020 20:16:58
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User entered 'mmHg'	System	08 Aug 2020 20:25:44
User entered empty.	System	08 Aug 2020 20:16:58

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:23
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 20:03:24



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:23
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:03:24

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:04:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:04:05

US3242051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	08 Aug 2020 20:04:05
	System	

US3242051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
	(b) (4), (b) (6)	
User entered '08 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:05

US3242051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
	(b) (4), (b) (6)	
User entered '15:49'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:05

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '08 Aug 2020 15:49'	(b) (4), (b) (6)	
	System	08 Aug 2020 20:04:05



US3242051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
	(b) (4), (b) (6)	
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:05

US3242051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:28
User entered 'ONCE'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:35
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:21

US3242051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:35
	(b) (4), (b) (6)	
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:21

US3242051

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:35
	(b) (4), (b) (6)	
User entered '15:42'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:21

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '8 Aug 2020 15:42'	(b) (4), (b) (6)	08 Aug 2020 20:04:21
	System	

US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:39
	(b) (4), (b) (6)	
User entered '8 Aug 2020'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36



US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36

US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36

US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:39
	(b) (4), (b) (6)	
User entered '15:30'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '8 Aug 2020 15:30'	(b) (4), (b) (6)	
	System	08 Aug 2020 20:04:36

US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36

US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:39
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	08 Aug 2020 20:28:31
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36

US3242051

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:39
	(b) (4), (b) (6)	
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Aug 2020 20:28:31
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Aug 2020 20:28:31
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Aug 2020 20:04:36
User entered empty.	Donna Toepfer (b) (4)	08 Aug 2020 20:04:36

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 20:04:36
	System	



US3242051

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:20:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	08 Aug 2020 20:04:42

**US3242051**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	(b) (4), (b) (6)	08 Aug 2020 20:04:42
	System	

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:21:55', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '68fcf3ca-2747-44c4-97ac-75843d984743' User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Aug 2020 20:22:14
	System	08 Aug 2020 20:22:14

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:22:02', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '68fcf3ca-2747-44c4-97ac-75843d984743' User entered '98.0'	(b) (4), (b) (6) System	08 Aug 2020 20:22:14
	System	08 Aug 2020 20:22:14

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:22:07', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '68fcf3ca-2747-44c4-97ac-75843d984743'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Aug 2020 20:22:14

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:22:11', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '68fcf3ca-2747-44c4-97ac-75843d984743' User entered '08 Aug 2020 16:22'	(b) (4), (b) (6) System	08 Aug 2020 20:22:14
	System	08 Aug 2020 20:22:14

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 16:09'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 18:39'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:17:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0b11c867-af1b-4585-aa50-4fafdd731181' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Aug 2020 00:17:52
	System	09 Aug 2020 00:17:52

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:17:35', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0b11c867-af1b-4585-aa50-4fafdd731181' User entered '98.3'	(b) (4), (b) (6) System	09 Aug 2020 00:17:52
	System	09 Aug 2020 00:17:52

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:17:40', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0b11c867-af1b-4585-aa50-4fafdd731181'	(b) (4), (b) (6)	
	System	09 Aug 2020 00:17:52
User entered 'No (N)'	System	09 Aug 2020 00:17:52

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:17:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0b11c867-af1b-4585-aa50-4fafdd731181' User entered '08 Aug 2020 20:17'	(b) (4), (b) (6) System	09 Aug 2020 00:17:52
	System	09 Aug 2020 00:17:52

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 19:34'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05



US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 2'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:45:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5138737f-fd46-4643-af99-be4df8e08797'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	09 Aug 2020 19:45:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:45:10', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5138737f-fd46-4643-af99-be4df8e08797' User entered '98.4'	(b) (4), (b) (6) System	09 Aug 2020 19:45:21
	System	09 Aug 2020 19:45:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:45:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5138737f-fd46-4643-af99-be4df8e08797'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 19:45:21

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:45:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5138737f-fd46-4643-af99-be4df8e08797'	(b) (4), (b) (6) System	09 Aug 2020 19:45:21
User entered '09 Aug 2020 15:45'	System	09 Aug 2020 19:45:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 3'	System	08 Aug 2020 20:04:05



US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:03', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3f9f24-e532-438e-8dd5-a547e95c6478' User entered 'Yes (Y)'	(b) (4), (b) (6) System	10 Aug 2020 18:08:21
	System	10 Aug 2020 18:08:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3f9f24-e532-438e-8dd5-a547e95c6478' User entered '97.9'	(b) (4), (b) (6) System	10 Aug 2020 18:08:21
	System	10 Aug 2020 18:08:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3f9f24-e532-438e-8dd5-a547e95c6478'	(b) (4), (b) (6) System	10 Aug 2020 18:08:21
User entered 'No (N)'	System	10 Aug 2020 18:08:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3f9f24-e532-438e-8dd5-a547e95c6478' User entered '10 Aug 2020 14:08'	(b) (4), (b) (6) System	10 Aug 2020 18:08:21
	System	10 Aug 2020 18:08:21

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 4'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:37:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0940d115-a941-4290-8559-11cb7a747864' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Aug 2020 21:38:23
	System	11 Aug 2020 21:38:23



US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:38:11', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0940d115-a941-4290-8559-11cb7a747864' User entered '97.9'	(b) (4), (b) (6) System	11 Aug 2020 21:38:23
	System	11 Aug 2020 21:38:23

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:38:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0940d115-a941-4290-8559-11cb7a747864'	(b) (4), (b) (6)	11 Aug 2020 21:38:23
User entered 'No (N)'	System	11 Aug 2020 21:38:23

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:38:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0940d115-a941-4290-8559-11cb7a747864'	(b) (4), (b) (6)	11 Aug 2020 21:38:23
User entered '11 Aug 2020 17:38'	System	11 Aug 2020 21:38:23

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 5'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f0134aac-f6cc-49ff-b562-b51b925ed113'	(b) (4), (b) (6)	
	System	13 Aug 2020 00:35:42
User entered 'Yes (Y)'	System	13 Aug 2020 00:35:42

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f0134aac-f6cc-49ff-b562-b51b925ed113' User entered '98.0'	(b) (4), (b) (6) System	13 Aug 2020 00:35:42
	System	13 Aug 2020 00:35:42



US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f0134aac-f6cc-49ff-b562-b51b925ed113'	(b) (4), (b) (6)	13 Aug 2020 00:35:42
User entered 'No (N)'	System	13 Aug 2020 00:35:42

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:41', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f0134aac-f6cc-49ff-b562-b51b925ed113'	(b) (4), (b) (6)	
	System	13 Aug 2020 00:35:42
User entered '12 Aug 2020 20:35'	System	13 Aug 2020 00:35:42

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 6'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:07', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a4069cb9-f99c-4ce6-b9ae-f81a34f9af28' User entered 'Yes (Y)'	(b) (4), (b) (6) System	13 Aug 2020 20:08:24
	System	13 Aug 2020 20:08:24

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:11', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a4069cb9-f99c-4ce6-b9ae-f81a34f9af28' User entered '98.3'	(b) (4), (b) (6) System	13 Aug 2020 20:08:24
	System	13 Aug 2020 20:08:24

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:14', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a4069cb9-f99c-4ce6-b9ae-f81a34f9af28'	(b) (4), (b) (6)	13 Aug 2020 20:08:24
User entered 'No (N)'	System	13 Aug 2020 20:08:24



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a4069cb9-f99c-4ce6-b9ae-f81a34f9af28'	(b) (4), (b) (6) System	13 Aug 2020 20:08:24
User entered '13 Aug 2020 16:08'	System	13 Aug 2020 20:08:24

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 7'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:18:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '42154e6c-4824-4637-b485-4b99197cd7f4' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:09
	System	14 Aug 2020 18:19:09

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:18:53', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '42154e6c-4824-4637-b485-4b99197cd7f4' User entered '98.0'	(b) (4), (b) (6) System	14 Aug 2020 18:19:09
	System	14 Aug 2020 18:19:09

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:18:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '42154e6c-4824-4637-b485-4b99197cd7f4'	(b) (4), (b) (6) System	14 Aug 2020 18:19:09
User entered 'No (N)'	System	14 Aug 2020 18:19:09

US3242051

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '42154e6c-4824-4637-b485-4b99197cd7f4' User entered '14 Aug 2020 14:19'	(b) (4), (b) (6) System	14 Aug 2020 18:19:09
	System	14 Aug 2020 18:19:09



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:08', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e61c63de-db95-4d6e-b86c-85d89293dee9' User entered 'None (1)'	(b) (4), (b) (6) System	08 Aug 2020 20:19:35
	System	08 Aug 2020 20:19:35

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e61c63de-db95-4d6e-b86c-85d89293dee9' User entered 'No (N)'	(b) (4), (b) (6) System	08 Aug 2020 20:19:35
	System	08 Aug 2020 20:19:35

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e61c63de-db95-4d6e-b86c-85d89293dee9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Aug 2020 20:19:35
	System	08 Aug 2020 20:19:35

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e61c63de-db95-4d6e-b86c-85d89293dee9' User entered '10'	(b) (4), (b) (6) System	08 Aug 2020 20:19:35
	System	08 Aug 2020 20:19:35

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:25', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e61c63de-db95-4d6e-b86c-85d89293dee9' User entered 'None (1)'	(b) (4), (b) (6) System	08 Aug 2020 20:19:35
	System	08 Aug 2020 20:19:35



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:30', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e61c63de-db95-4d6e-b86c-85d89293dee9' User entered '08 Aug 2020 16:19'	(b) (4), (b) (6) System	08 Aug 2020 20:19:35
	System	08 Aug 2020 20:19:35

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 16:09'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 18:39'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:17:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '6b1feccf-7e88-49d7-827d-c33012290b8a' User entered 'None (1)'	(b) (4), (b) (6) System	09 Aug 2020 00:18:21
	System	09 Aug 2020 00:18:21

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:18:04', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '6b1feccf-7e88-49d7-827d-c33012290b8a' User entered 'No (N)'	(b) (4), (b) (6) System	09 Aug 2020 00:18:21
	System	09 Aug 2020 00:18:21

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:18:08', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '6b1feccf-7e88-49d7-827d-c33012290b8a' User entered 'No (N)'	(b) (4), (b) (6) System	09 Aug 2020 00:18:21
	System	09 Aug 2020 00:18:21

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:18:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '6b1feccf-7e88-49d7-827d-c33012290b8a' User entered 'None (1)'	(b) (4), (b) (6) System	09 Aug 2020 00:18:21
	System	09 Aug 2020 00:18:21



US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:18:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '6b1feccf-7e88-49d7-827d-c33012290b8a' User entered '08 Aug 2020 20:18'	(b) (4), (b) (6) System	09 Aug 2020 00:18:21
	System	09 Aug 2020 00:18:21

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 19:34'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 2'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:44:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fd17433-d03e-4b36-bd29-428084745883'	(b) (4), (b) (6) System	09 Aug 2020 19:44:24
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 19:44:24

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:44:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fd17433-d03e-4b36-bd29-428084745883'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 19:44:24

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:44:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fd17433-d03e-4b36-bd29-428084745883'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Aug 2020 19:44:24

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:44:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fd17433-d03e-4b36-bd29-428084745883'	(b) (4), (b) (6) System	09 Aug 2020 19:44:24
User entered 'None (1)'	System	09 Aug 2020 19:44:24



US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:44:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fd17433-d03e-4b36-bd29-428084745883' User entered '09 Aug 2020 15:44'	(b) (4), (b) (6) System	09 Aug 2020 19:44:24
	System	09 Aug 2020 19:44:24

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 3'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '993f7e19-df23-4191-ac50-6dc4b65c2952'	(b) (4), (b) (6) System	10 Aug 2020 18:08:54
User entered 'None (1)'	System	10 Aug 2020 18:08:54

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:36', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '993f7e19-df23-4191-ac50-6dc4b65c2952'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Aug 2020 18:08:54

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:39', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '993f7e19-df23-4191-ac50-6dc4b65c2952' User entered 'No (N)'	(b) (4), (b) (6) System	10 Aug 2020 18:08:54
	System	10 Aug 2020 18:08:54

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '993f7e19-df23-4191-ac50-6dc4b65c2952'	(b) (4), (b) (6)	10 Aug 2020 18:08:54
User entered 'None (1)'	System	10 Aug 2020 18:08:54



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:52', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '993f7e19-df23-4191-ac50-6dc4b65c2952' User entered '10 Aug 2020 14:08'	(b) (4), (b) (6) System	10 Aug 2020 18:08:54
	System	10 Aug 2020 18:08:54

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 4'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:35:43', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f790bb10-9ff8-4346-ab64-1cfd0a1a7630'	(b) (4), (b) (6) System	11 Aug 2020 21:36:02
User entered 'None (1)'	System	11 Aug 2020 21:36:02

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:35:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f790bb10-9ff8-4346-ab64-1cfd0a1a7630' User entered 'No (N)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:02
	System	11 Aug 2020 21:36:02

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:35:51', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f790bb10-9ff8-4346-ab64-1cfd0a1a7630'	(b) (4), (b) (6)	11 Aug 2020 21:36:02
User entered 'No (N)'	System	11 Aug 2020 21:36:02

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:35:56', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f790bb10-9ff8-4346-ab64-1cfd0a1a7630'	(b) (4), (b) (6) System	11 Aug 2020 21:36:02
User entered 'None (1)'	System	11 Aug 2020 21:36:02



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f790bb10-9ff8-4346-ab64-1cfd0a1a7630' User entered '11 Aug 2020 17:36'	(b) (4), (b) (6) System	11 Aug 2020 21:36:02
	System	11 Aug 2020 21:36:02

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 5'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3654c1c9-9e5a-4065-82c0-a7dba4633ed7' User entered 'None (1)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:06
	System	13 Aug 2020 00:36:06

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3654c1c9-9e5a-4065-82c0-a7dba4633ed7' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:06
	System	13 Aug 2020 00:36:06

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:55', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3654c1c9-9e5a-4065-82c0-a7dba4633ed7' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:06
	System	13 Aug 2020 00:36:06

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:35:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3654c1c9-9e5a-4065-82c0-a7dba4633ed7' User entered 'None (1)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:06
	System	13 Aug 2020 00:36:06



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3654c1c9-9e5a-4065-82c0-a7dba4633ed7' User entered '12 Aug 2020 20:36'	(b) (4), (b) (6) System	13 Aug 2020 00:36:06
	System	13 Aug 2020 00:36:06

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 6'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:23', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8424436c-92e6-41ca-b6b9-d1e41e64b2b2'	(b) (4), (b) (6) System	13 Aug 2020 20:08:37
User entered 'None (1)'	System	13 Aug 2020 20:08:37

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8424436c-92e6-41ca-b6b9-d1e41e64b2b2' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 20:08:37
	System	13 Aug 2020 20:08:37

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8424436c-92e6-41ca-b6b9-d1e41e64b2b2' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 20:08:37
	System	13 Aug 2020 20:08:37

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8424436c-92e6-41ca-b6b9-d1e41e64b2b2'	(b) (4), (b) (6) System	13 Aug 2020 20:08:37
User entered 'None (1)'	System	13 Aug 2020 20:08:37



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:35', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8424436c-92e6-41ca-b6b9-d1e41e64b2b2'	(b) (4), (b) (6) System	13 Aug 2020 20:08:37
User entered '13 Aug 2020 16:08'	System	13 Aug 2020 20:08:37

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 7'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:10', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'af9dbb9e-f37d-41b0-afcf-f998c4ab6763'	(b) (4), (b) (6) System	14 Aug 2020 18:19:27
User entered 'None (1)'	System	14 Aug 2020 18:19:27

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:14', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'af9dbb9e-f37d-41b0-afcf-f998c4ab6763' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:27
	System	14 Aug 2020 18:19:27

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'af9dbb9e-f37d-41b0-afcf-f998c4ab6763' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:27
	System	14 Aug 2020 18:19:27

US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'af9dbb9e-f37d-41b0-afcf-f998c4ab6763'	(b) (4), (b) (6) System	14 Aug 2020 18:19:27
User entered 'None (1)'	System	14 Aug 2020 18:19:27



US3242051

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:24', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'af9dbb9e-f37d-41b0-afcf-f998c4ab6763' User entered '14 Aug 2020 14:19'	(b) (4), (b) (6) System	14 Aug 2020 18:19:27
	System	14 Aug 2020 18:19:27

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:36', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:53', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:19:56', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'None (0)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:20:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered 'No (N)'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T16:20:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '682438ae-50c5-4a71-be57-d6fd250ef45a' User entered '08 Aug 2020 16:20'	(b) (4), (b) (6) System	08 Aug 2020 20:20:10
	System	08 Aug 2020 20:20:10

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 16:09'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 18:39'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:18:31', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:18:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:19:01', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:19:06', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:19:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0'	(b) (4), (b) (6)	
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:19:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:19:28', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered 'No (N)'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-08T20:19:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'adb02eca-b8f7-4e71-8487-55d4984190d0' User entered '08 Aug 2020 20:19'	(b) (4), (b) (6) System	09 Aug 2020 00:19:37
	System	09 Aug 2020 00:19:37

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '08 Aug 2020 19:34'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '09 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 2'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 19:43:58
	System	09 Aug 2020 19:43:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:30', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441'	(b) (4), (b) (6)	
	System	09 Aug 2020 19:43:58
User entered 'No interference with activity (1)'	System	09 Aug 2020 19:43:58

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 19:43:58
	System	09 Aug 2020 19:43:58

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:36', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 19:43:58
	System	09 Aug 2020 19:43:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 19:43:58
	System	09 Aug 2020 19:43:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:48', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441' User entered 'None (0)'	(b) (4), (b) (6) System	09 Aug 2020 19:43:58
	System	09 Aug 2020 19:43:58



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:54', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441'	(b) (4), (b) (6)	
	System	09 Aug 2020 19:43:58
User entered 'No (N)'	System	09 Aug 2020 19:43:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-09T15:43:56', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a0570870-694f-4575-b227-1509736ac441' User entered '09 Aug 2020 15:43'	(b) (4), (b) (6) System	09 Aug 2020 19:43:58
	System	09 Aug 2020 19:43:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '09 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '10 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 3'	System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:08:58', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:01', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:04', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:07', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:10', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'None (0)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered 'No (N)'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-10T14:09:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9cca2c0d-719a-4e14-970a-9de27c0e559a' User entered '10 Aug 2020 14:09'	(b) (4), (b) (6) System	10 Aug 2020 18:09:25
	System	10 Aug 2020 18:09:25

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '10 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 4'	System	08 Aug 2020 20:04:05



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
	System	11 Aug 2020 21:36:41

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:14', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
	System	11 Aug 2020 21:36:41

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
	System	11 Aug 2020 21:36:41

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
	System	11 Aug 2020 21:36:41

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:24', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
	System	11 Aug 2020 21:36:41

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672' User entered 'None (0)'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
	System	11 Aug 2020 21:36:41

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672'	(b) (4), (b) (6)	11 Aug 2020 21:36:41
User entered 'No (N)'	System	11 Aug 2020 21:36:41

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-11T17:36:35', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f7be66c-31f0-484c-8ea9-4c9f6bbfe672'	(b) (4), (b) (6) System	11 Aug 2020 21:36:41
User entered '11 Aug 2020 17:36'	System	11 Aug 2020 21:36:41



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 5'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:21', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:24', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-12T20:36:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c2d47f12-f430-4392-aa1c-308b1b19c31e' User entered '12 Aug 2020 20:36'	(b) (4), (b) (6) System	13 Aug 2020 00:36:34
	System	13 Aug 2020 00:36:34

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 6'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:41', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:52', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:54', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'None (0)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:08:58', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered 'No (N)'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-13T16:09:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1db0ad96-15b4-4dcc-955f-2f3d633eac3b' User entered '13 Aug 2020 16:09'	(b) (4), (b) (6) System	13 Aug 2020 20:09:12
	System	13 Aug 2020 20:09:12

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05



US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 7'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:40', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'None (0)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

US3242051

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:53', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered 'No (N)'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58



**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-08-14T14:19:55', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fb3a0a76-0ed4-43f5-84bb-8551a8a8cf1b' User entered '14 Aug 2020 14:19'	(b) (4), (b) (6) System	14 Aug 2020 18:19:58
	System	14 Aug 2020 18:19:58

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Aug 2020 11:59'	(b) (4), (b) (6) System	08 Aug 2020 20:04:05

US3242051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:20:48
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	17 Aug 2020 22:07:24
	(b) (4)	

US3242051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:20:48
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	Grace Newville (b) (4)	17 Aug 2020 22:07:24
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:20:48
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	17 Aug 2020 22:07:24
	(b) (4)	

US3242051

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:20:48
	(b) (4), (b) (6)	
User entered empty.	Grace Newville (b) (4)	17 Aug 2020 22:07:24
	(b) (4)	

US3242051

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:20:52
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	17 Aug 2020 22:07:12
	(b) (4)	



**US3242051**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	(b) (4), (b) (6)	17 Aug 2020 22:07:12
	System	

**US3242051**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 20:03:48

**US3242051**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:02
	(b) (4), (b) (6)	
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 20:03:48

**US3242051**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:02
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Aug 2020 20:03:48

US3242051

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:02
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 20:03:48

US3242051

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:12
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 20:03:36

**US3242051**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	(b) (4), (b) (6)	24 Aug 2020 20:03:36
	System	

US3242051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:18
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	01 Sep 2020 15:38:01
	(b) (4)	



US3242051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:18
	(b) (4), (b) (6)	
User entered '1 Sep 2020'	Grace Newville (b) (4)	01 Sep 2020 15:38:01
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:18
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	01 Sep 2020 15:38:01
	(b) (4)	

US3242051

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:18
	(b) (4), (b) (6)	
User entered empty.	Grace Newville (b) (4)	01 Sep 2020 15:38:01
	(b) (4)	

US3242051

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:22
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Grace Newville (b) (4)	01 Sep 2020 15:38:04
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	System	01 Sep 2020 15:38:04

US3242051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:22:43

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:22:43

US3242051

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	11 Sep 2020 20:22:43



**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'VISIT2'	System	11 Sep 2020 20:22:43

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '15:25'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '11 Sep 2020 15:25'	(b) (4), (b) (6)	11 Sep 2020 21:13:42
	System	

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '98.2' F	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42



US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '80'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '128'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '80'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42



US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16:58'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '11 Sep 2020 16:58'	(b) (4), (b) (6)	11 Sep 2020 21:13:42
	System	

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '97.7' F	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42



US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '72'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'bpm'	System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '126'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '78'	Donna Toepfer (b) (4)	11 Sep 2020 21:13:42



US3242051

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 21:13:42

US3242051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 20:22:53

US3242051

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:22:53

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	11 Sep 2020 20:47:28
	System	

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:47:28



US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16:28'	Donna Toepfer (b) (4)	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '11 Sep 2020 16:28'	(b) (4), (b) (6)	11 Sep 2020 20:47:28
	System	

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'ONCE'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:08

US3242051

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:08

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16:10'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:08



**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '11 Sep 2020 16:10'	(b) (4), (b) (6)	11 Sep 2020 20:23:08
	System	

US3242051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '11 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25

US3242051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25

US3242051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25

US3242051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16:00'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '11 Sep 2020 16:00'	(b) (4), (b) (6)	11 Sep 2020 20:23:25
	System	

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25

US3242051

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25



**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:11:53**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 20:23:25

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:23:25
	System	

US3242051

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 20:23:30

**US3242051**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	System	11 Sep 2020 20:23:30

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:10', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a957b312-d54c-4263-bb22-50f96ed73642'	(b) (4), (b) (6)	11 Sep 2020 21:00:33
User entered 'Yes (Y)'	System	11 Sep 2020 21:00:33

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a957b312-d54c-4263-bb22-50f96ed73642' User entered '97.7'	(b) (4), (b) (6) System	11 Sep 2020 21:00:33
	System	11 Sep 2020 21:00:33

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:21', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a957b312-d54c-4263-bb22-50f96ed73642'	(b) (4), (b) (6)	11 Sep 2020 21:00:33
User entered 'No (N)'	System	11 Sep 2020 21:00:33



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a957b312-d54c-4263-bb22-50f96ed73642'	(b) (4), (b) (6) System	11 Sep 2020 21:00:33
User entered '11 Sep 2020 17:00'	System	11 Sep 2020 21:00:33

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 16:48'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 19:18'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd220c8ee-6489-4f75-84bc-41a2617423e3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 00:15:31
	System	12 Sep 2020 00:15:31

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd220c8ee-6489-4f75-84bc-41a2617423e3' User entered '98.0'	(b) (4), (b) (6) System	12 Sep 2020 00:15:31
	System	12 Sep 2020 00:15:31

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:25', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd220c8ee-6489-4f75-84bc-41a2617423e3'	(b) (4), (b) (6)	12 Sep 2020 00:15:31
User entered 'No (N)'	System	12 Sep 2020 00:15:31

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd220c8ee-6489-4f75-84bc-41a2617423e3' User entered '11 Sep 2020 20:15'	(b) (4), (b) (6) System	12 Sep 2020 00:15:31
	System	12 Sep 2020 00:15:31



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 20:13'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 2'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1a0c2bb1-9df2-4c2a-b06b-9449c330bbce' User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 23:40:32
	System	12 Sep 2020 23:40:32

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:23', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1a0c2bb1-9df2-4c2a-b06b-9449c330bbce' User entered '98.2'	(b) (4), (b) (6) System	12 Sep 2020 23:40:32
	System	12 Sep 2020 23:40:32

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:26', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1a0c2bb1-9df2-4c2a-b06b-9449c330bbce' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 23:40:32
	System	12 Sep 2020 23:40:32

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:30', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1a0c2bb1-9df2-4c2a-b06b-9449c330bbce' User entered '12 Sep 2020 19:40'	(b) (4), (b) (6) System	12 Sep 2020 23:40:32
	System	12 Sep 2020 23:40:32

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28



US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 3'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:07:35', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c0022003-78f3-4dc4-88d3-9412b3a170ac'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	13 Sep 2020 22:07:52

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:07:41', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c0022003-78f3-4dc4-88d3-9412b3a170ac' User entered '98.7'	(b) (4), (b) (6) System	13 Sep 2020 22:07:52
	System	13 Sep 2020 22:07:52

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:07:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c0022003-78f3-4dc4-88d3-9412b3a170ac'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Sep 2020 22:07:52

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:07:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c0022003-78f3-4dc4-88d3-9412b3a170ac' User entered '13 Sep 2020 18:07'	(b) (4), (b) (6) System	13 Sep 2020 22:07:52
	System	13 Sep 2020 22:07:52

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28



US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 4'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:36', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '44886e9f-cf2a-467c-9937-519e9ca78d3d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Sep 2020 22:06:49
	System	14 Sep 2020 22:06:49

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:40', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '44886e9f-cf2a-467c-9937-519e9ca78d3d' User entered '97.7'	(b) (4), (b) (6) System	14 Sep 2020 22:06:49
	System	14 Sep 2020 22:06:49

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '44886e9f-cf2a-467c-9937-519e9ca78d3d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 22:06:49
	System	14 Sep 2020 22:06:49

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '44886e9f-cf2a-467c-9937-519e9ca78d3d' User entered '14 Sep 2020 18:06'	(b) (4), (b) (6) System	14 Sep 2020 22:06:49
	System	14 Sep 2020 22:06:49

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 5'	System	11 Sep 2020 20:47:28



US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:19:40', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8140da74-7fe2-47de-85fc-1fe20b090d1a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 01:19:54
	System	16 Sep 2020 01:19:54

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:19:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8140da74-7fe2-47de-85fc-1fe20b090d1a' User entered '98.2'	(b) (4), (b) (6) System	16 Sep 2020 01:19:54
	System	16 Sep 2020 01:19:54

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:19:48', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8140da74-7fe2-47de-85fc-1fe20b090d1a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:19:54
	System	16 Sep 2020 01:19:54

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:19:52', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8140da74-7fe2-47de-85fc-1fe20b090d1a' User entered '15 Sep 2020 21:19'	(b) (4), (b) (6) System	16 Sep 2020 01:19:54
	System	16 Sep 2020 01:19:54

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 6'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:21', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f0eef5c-7815-458f-8a76-7a611cd97c79'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	17 Sep 2020 13:30:38



US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:26', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f0eef5c-7815-458f-8a76-7a611cd97c79' User entered '97.7'	(b) (4), (b) (6) System	17 Sep 2020 13:30:38
	System	17 Sep 2020 13:30:38

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f0eef5c-7815-458f-8a76-7a611cd97c79'	(b) (4), (b) (6)	17 Sep 2020 13:30:38
User entered 'No (N)'	System	17 Sep 2020 13:30:38

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3f0eef5c-7815-458f-8a76-7a611cd97c79' User entered '17 Sep 2020 09:30'	(b) (4), (b) (6) System	17 Sep 2020 13:30:38
	System	17 Sep 2020 13:30:38

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 7'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:50:45', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9f691ddc-3525-4fe7-b268-8c212cd55e8d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Sep 2020 21:51:18
	System	17 Sep 2020 21:51:18

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:08', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9f691ddc-3525-4fe7-b268-8c212cd55e8d' User entered '98.4'	(b) (4), (b) (6) System	17 Sep 2020 21:51:18
	System	17 Sep 2020 21:51:18



US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9f691ddc-3525-4fe7-b268-8c212cd55e8d' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 21:51:18
	System	17 Sep 2020 21:51:18

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9f691ddc-3525-4fe7-b268-8c212cd55e8d' User entered '17 Sep 2020 17:51'	(b) (4), (b) (6) System	17 Sep 2020 21:51:18
	System	17 Sep 2020 21:51:18

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dcb51108-dadb-4d17-96db-54de620a7ca6'	(b) (4), (b) (6)	11 Sep 2020 21:01:09
User entered 'None (1)'	System	11 Sep 2020 21:01:09

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dcb51108-dadb-4d17-96db-54de620a7ca6' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 21:01:09
	System	11 Sep 2020 21:01:09

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:00:56', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dcb51108-dadb-4d17-96db-54de620a7ca6' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 21:01:09
	System	11 Sep 2020 21:01:09



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dcb51108-dadb-4d17-96db-54de620a7ca6'	(b) (4), (b) (6)	11 Sep 2020 21:01:09
User entered 'None (1)'	System	11 Sep 2020 21:01:09

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:04', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dcb51108-dadb-4d17-96db-54de620a7ca6' User entered '11 Sep 2020 17:01'	(b) (4), (b) (6) System	11 Sep 2020 21:01:09
	System	11 Sep 2020 21:01:09

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 16:48'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 19:18'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c92ccb5f-e928-47f9-a5d8-83fcc99ff832'	(b) (4), (b) (6)	12 Sep 2020 00:16:02
User entered 'None (1)'	System	12 Sep 2020 00:16:02

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c92ccb5f-e928-47f9-a5d8-83fcc99ff832'	(b) (4), (b) (6)	
	System	12 Sep 2020 00:16:02
User entered 'No (N)'	System	12 Sep 2020 00:16:02

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c92ccb5f-e928-47f9-a5d8-83fcc99ff832' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:02
	System	12 Sep 2020 00:16:02



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:15:51', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c92ccb5f-e928-47f9-a5d8-83fcc99ff832'	(b) (4), (b) (6)	12 Sep 2020 00:16:02
User entered 'None (1)'	System	12 Sep 2020 00:16:02

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:01', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c92ccb5f-e928-47f9-a5d8-83fcc99ff832'	(b) (4), (b) (6) System	12 Sep 2020 00:16:02
User entered '11 Sep 2020 20:16'	System	12 Sep 2020 00:16:02

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 20:13'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 2'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:34', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0f5b04b5-d374-4880-8d01-710025fdb813'	(b) (4), (b) (6) System	12 Sep 2020 23:40:54
User entered 'None (1)'	System	12 Sep 2020 23:40:54

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0f5b04b5-d374-4880-8d01-710025fdb813' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 23:40:54
	System	12 Sep 2020 23:40:54

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:40', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0f5b04b5-d374-4880-8d01-710025fdb813' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 23:40:54
	System	12 Sep 2020 23:40:54



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0f5b04b5-d374-4880-8d01-710025fdb813'	(b) (4), (b) (6)	12 Sep 2020 23:40:54
User entered 'None (1)'	System	12 Sep 2020 23:40:54

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0f5b04b5-d374-4880-8d01-710025fdb813'	(b) (4), (b) (6)	12 Sep 2020 23:40:54
User entered '12 Sep 2020 19:40'	System	12 Sep 2020 23:40:54

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 3'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:07:54', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '809a93a2-45ae-44bd-aa2f-b5148a5b3913'	(b) (4), (b) (6) System	13 Sep 2020 22:08:36
User entered 'None (1)'	System	13 Sep 2020 22:08:36

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '809a93a2-45ae-44bd-aa2f-b5148a5b3913' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 22:08:36
	System	13 Sep 2020 22:08:36

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:21', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '809a93a2-45ae-44bd-aa2f-b5148a5b3913' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 22:08:36
	System	13 Sep 2020 22:08:36



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:28', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '809a93a2-45ae-44bd-aa2f-b5148a5b3913'	(b) (4), (b) (6)	13 Sep 2020 22:08:36
User entered 'None (1)'	System	13 Sep 2020 22:08:36

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:31', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '809a93a2-45ae-44bd-aa2f-b5148a5b3913' User entered '13 Sep 2020 18:08'	(b) (4), (b) (6) System	13 Sep 2020 22:08:36
	System	13 Sep 2020 22:08:36

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 4'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'cc65e97c-b5d6-43d6-b96b-a1149d0303c5' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:09
	System	14 Sep 2020 22:07:09

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:55', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'cc65e97c-b5d6-43d6-b96b-a1149d0303c5' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:09
	System	14 Sep 2020 22:07:09

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:06:58', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'cc65e97c-b5d6-43d6-b96b-a1149d0303c5' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:09
	System	14 Sep 2020 22:07:09



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:02', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'cc65e97c-b5d6-43d6-b96b-a1149d0303c5' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:09
	System	14 Sep 2020 22:07:09

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'cc65e97c-b5d6-43d6-b96b-a1149d0303c5' User entered '14 Sep 2020 18:07'	(b) (4), (b) (6) System	14 Sep 2020 22:07:09
	System	14 Sep 2020 22:07:09

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 5'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:19:56', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7d9c5cef-2c38-41af-84bd-1e87e54aba3d'	(b) (4), (b) (6) System	16 Sep 2020 01:20:40
User entered 'None (1)'	System	16 Sep 2020 01:20:40

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:19:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7d9c5cef-2c38-41af-84bd-1e87e54aba3d' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:20:40
	System	16 Sep 2020 01:20:40

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:03', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7d9c5cef-2c38-41af-84bd-1e87e54aba3d' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:20:40
	System	16 Sep 2020 01:20:40



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:31', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7d9c5cef-2c38-41af-84bd-1e87e54aba3d'	(b) (4), (b) (6)	16 Sep 2020 01:20:40
User entered 'None (1)'	System	16 Sep 2020 01:20:40

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:36', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7d9c5cef-2c38-41af-84bd-1e87e54aba3d' User entered '15 Sep 2020 21:20'	(b) (4), (b) (6) System	16 Sep 2020 01:20:40
	System	16 Sep 2020 01:20:40

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 6'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c95400a6-f2b3-41ba-a21a-b61ed0779106'	(b) (4), (b) (6) System	17 Sep 2020 13:30:56
User entered 'None (1)'	System	17 Sep 2020 13:30:56

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:39', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c95400a6-f2b3-41ba-a21a-b61ed0779106' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 13:30:56
	System	17 Sep 2020 13:30:56

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c95400a6-f2b3-41ba-a21a-b61ed0779106' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 13:30:56
	System	17 Sep 2020 13:30:56



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c95400a6-f2b3-41ba-a21a-b61ed0779106'	(b) (4), (b) (6)	17 Sep 2020 13:30:56
User entered 'None (1)'	System	17 Sep 2020 13:30:56

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:30:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c95400a6-f2b3-41ba-a21a-b61ed0779106' User entered '17 Sep 2020 09:30'	(b) (4), (b) (6) System	17 Sep 2020 13:30:56
	System	17 Sep 2020 13:30:56

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 7'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:36', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '038d0274-11a2-4a06-97a9-9ac44147decc'	(b) (4), (b) (6)	17 Sep 2020 21:52:06
User entered 'None (1)'	System	17 Sep 2020 21:52:06

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:41', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '038d0274-11a2-4a06-97a9-9ac44147decc' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 21:52:06
	System	17 Sep 2020 21:52:06

US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '038d0274-11a2-4a06-97a9-9ac44147decc' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 21:52:06
	System	17 Sep 2020 21:52:06



US3242051

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:51:57', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '038d0274-11a2-4a06-97a9-9ac44147decc'	(b) (4), (b) (6)	17 Sep 2020 21:52:06
User entered 'None (1)'	System	17 Sep 2020 21:52:06

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:01', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '038d0274-11a2-4a06-97a9-9ac44147decc' User entered '17 Sep 2020 17:52'	(b) (4), (b) (6) System	17 Sep 2020 21:52:06
	System	17 Sep 2020 21:52:06

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3'	(b) (4), (b) (6)	11 Sep 2020 21:01:34
User entered 'None (0)'	System	11 Sep 2020 21:01:34

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:01:34
	System	11 Sep 2020 21:01:34

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3'	(b) (4), (b) (6) System	11 Sep 2020 21:01:34
User entered 'None (0)'	System	11 Sep 2020 21:01:34



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:22', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:01:34
	System	11 Sep 2020 21:01:34

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:25', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3'	(b) (4), (b) (6)	11 Sep 2020 21:01:34
User entered 'None (0)'	System	11 Sep 2020 21:01:34

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 21:01:34
	System	11 Sep 2020 21:01:34

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:30', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3'	(b) (4), (b) (6)	11 Sep 2020 21:01:34
User entered 'No (N)'	System	11 Sep 2020 21:01:34

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T17:01:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '83b5fb57-5d6f-4994-a27a-9d8ce176efa3'	(b) (4), (b) (6) System	11 Sep 2020 21:01:34
User entered '11 Sep 2020 17:01'	System	11 Sep 2020 21:01:34

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 16:48'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 19:18'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:47:28



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
User entered 'No interference with activity (1)'	System	12 Sep 2020 00:16:45

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
User entered 'No interference with activity (1)'	System	12 Sep 2020 00:16:45

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
	System	12 Sep 2020 00:16:45

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:26', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
	System	12 Sep 2020 00:16:45

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
	System	12 Sep 2020 00:16:45

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
	System	12 Sep 2020 00:16:45

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:39', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
	System	12 Sep 2020 00:16:45

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-11T20:16:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'fd3e2d60-de9d-4a22-b38c-5fcb8dd19a01' User entered '11 Sep 2020 20:16'	(b) (4), (b) (6) System	12 Sep 2020 00:16:45
	System	12 Sep 2020 00:16:45



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '11 Sep 2020 20:13'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 2'	System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:40:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c'	(b) (4), (b) (6)	
	System	12 Sep 2020 23:41:32
User entered 'No interference with activity (1)'	System	12 Sep 2020 23:41:32

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:21', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:24', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered 'None (0)'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-12T19:41:30', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'a3d10ded-6dc6-4fcf-b534-a1c7811c9e7c' User entered '12 Sep 2020 19:41'	(b) (4), (b) (6) System	12 Sep 2020 23:41:32
	System	12 Sep 2020 23:41:32

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 3'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:43', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:45', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:52', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:54', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered 'None (0)'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:08:57', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545'	(b) (4), (b) (6)	
User entered 'No (N)'	System	13 Sep 2020 22:09:06

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-13T18:09:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '819671c4-164f-4caf-91b1-f90a72ddc545' User entered '13 Sep 2020 18:09'	(b) (4), (b) (6) System	13 Sep 2020 22:09:06
	System	13 Sep 2020 22:09:06

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 4'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:28
	System	14 Sep 2020 22:07:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:11', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43'	(b) (4), (b) (6)	
User entered 'None (0)'	System	14 Sep 2020 22:07:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:14', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:28
	System	14 Sep 2020 22:07:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:28
	System	14 Sep 2020 22:07:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:28
	System	14 Sep 2020 22:07:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 22:07:28
	System	14 Sep 2020 22:07:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:24', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43'	(b) (4), (b) (6)	
User entered 'No (N)'	System	14 Sep 2020 22:07:28



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-14T18:07:26', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7fddea8e-db7b-4bf2-b8f8-26fc9f2e3e43' User entered '14 Sep 2020 18:07'	(b) (4), (b) (6) System	14 Sep 2020 22:07:28
	System	14 Sep 2020 22:07:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 5'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:45', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:52', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:55', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:20:57', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:21:02', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-15T21:21:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '57b17995-0210-4a2b-8cf7-45b2e07ed326' User entered '15 Sep 2020 21:21'	(b) (4), (b) (6) System	16 Sep 2020 01:21:08
	System	16 Sep 2020 01:21:08

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 6'	System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:03', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:07', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:11', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:15', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T09:31:18', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5a8b9217-fc71-4311-9e52-f6fe6b914beb' User entered '17 Sep 2020 09:31'	(b) (4), (b) (6) System	17 Sep 2020 13:31:22
	System	17 Sep 2020 13:31:22

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28



**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	11 Sep 2020 20:47:28
User entered 'Day 7'	System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:32', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:30', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:29', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:28', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:33', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35



US3242051

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:37', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-09-17T17:52:40', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'aff77aaf-61e2-44e0-915b-8ab73691ca6d' User entered '17 Sep 2020 17:52'	(b) (4), (b) (6) System	17 Sep 2020 21:53:35
	System	17 Sep 2020 21:53:35

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:11:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	11 Sep 2020 20:47:28

**US3242051**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Sep 2020 13:48:15
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '21 Sep 2020'	Grace Newville (b) (4)	21 Sep 2020 13:48:15
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	21 Sep 2020 13:48:15
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Grace Newville (b) (4)	21 Sep 2020 13:48:15
	(b) (4)	



US3242051

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Grace Newville (b) (4)	21 Sep 2020 13:48:18
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	System	21 Sep 2020 13:48:18

**US3242051**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Grace Newville (b) (4)	27 Sep 2020 16:02:23
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '27 Sep 2020'	Grace Newville (b) (4)	27 Sep 2020 16:02:23
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	27 Sep 2020 16:02:23
	(b) (4)	

US3242051

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Grace Newville (b) (4)	27 Sep 2020 16:02:23
	(b) (4)	

US3242051

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Grace Newville (b) (4)	27 Sep 2020 16:02:26
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	System	27 Sep 2020 16:02:26



**US3242051**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Oct 2020 14:39:05
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '2 Oct 2020'	Erynn McKinley (b) (4)	05 Oct 2020 14:39:05
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	05 Oct 2020 14:39:05
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Erynn McKinley (b) (4)	05 Oct 2020 14:39:05
	(b) (4)	

US3242051

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Oct 2020 14:39:09
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	(b) (4), (b) (6) System	05 Oct 2020 14:39:09

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 20:23:35
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 20:23:35
	(b) (4)	



US3242051

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[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 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	09 Oct 2020 20:23:35
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'VISIT3'	System	09 Oct 2020 20:23:35

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '14:46'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '9 Oct 2020 14:46'	(b) (4), (b) (6)	09 Oct 2020 20:24:05
	System	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '97.9' F	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	



**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '88'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'bpm'	System	09 Oct 2020 20:24:05

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '16'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'breaths/min'	(b) (4), (b) (6)	09 Oct 2020 20:24:05
	System	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '130'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6)	09 Oct 2020 20:24:05
	System	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '88'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:05
	(b) (4)	



**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'mmHg'	(b) (4), (b) (6) System	09 Oct 2020 20:24:05

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'No (N)'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:09
	(b) (4)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered empty.	Erynn McKinley (b) (4)	09 Oct 2020 20:24:09
	(b) (4)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:15
	(b) (4)	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '9 Oct 2020'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:15
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered '15:16'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:15
	(b) (4)	



**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered '9 Oct 2020 15:16'	(b) (4), (b) (6)	09 Oct 2020 20:24:15
	System	

US3242051

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:10:11
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	09 Oct 2020 20:24:18
	(b) (4)	

**US3242051**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 20:24:18
	System	

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 64'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-09T15:18:39', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '97128778-162e-4ae6-99df-f589fab4417c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 19:18:57
	System	09 Oct 2020 19:18:57

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-09T15:18:43', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '97128778-162e-4ae6-99df-f589fab4417c' User entered 'No (N)'	(b) (4), (b) (6) System	09 Oct 2020 19:18:57
	System	09 Oct 2020 19:18:57

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-09T15:18:53', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '97128778-162e-4ae6-99df-f589fab4417c' User entered '09 Oct 2020 15:18:53'	(b) (4), (b) (6) System	09 Oct 2020 19:18:57
	System	09 Oct 2020 19:18:57

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 20:04:05



**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 71'	System	08 Aug 2020 20:04:05

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

[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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-15T14:51:13', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dff3cd87-adc8-4f5d-a239-9360cb0b9eef' User entered 'No (N)'	(b) (4), (b) (6) System	15 Oct 2020 18:51:23
	System	15 Oct 2020 18:51:23

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-15T14:51:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dff3cd87-adc8-4f5d-a239-9360cb0b9eef'	(b) (4), (b) (6)	15 Oct 2020 18:51:23
User entered 'No (N)'	System	15 Oct 2020 18:51:23

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-15T14:51:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dff3cd87-adc8-4f5d-a239-9360cb0b9eef' User entered '15 Oct 2020 14:51:20'	(b) (4), (b) (6) System	15 Oct 2020 18:51:23
	System	15 Oct 2020 18:51:23

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 78'	System	08 Aug 2020 20:04:05



US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

[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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-24T12:32:08', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5cfa3e7d-1bfe-43f5-890c-ef12bf936489'	(b) (4), (b) (6)	24 Oct 2020 16:32:19
User entered 'No (N)'	System	24 Oct 2020 16:32:19

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-24T12:32:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5cfa3e7d-1bfe-43f5-890c-ef12bf936489'	(b) (4), (b) (6)	24 Oct 2020 16:32:19
User entered 'No (N)'	System	24 Oct 2020 16:32:19

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-10-24T12:32:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5cfa3e7d-1bfe-43f5-890c-ef12bf936489' User entered '24 Oct 2020 12:32:16'	(b) (4), (b) (6) System	24 Oct 2020 16:32:19
	System	24 Oct 2020 16:32:19

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 20:04:05

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 92'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-06T14:04:44', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'abb80386-f1da-4043-a595-1c6003c53284' User entered 'Yes (Y)'	(b) (4), (b) (6) System	06 Nov 2020 19:05:28
	System	06 Nov 2020 19:05:28

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-06T14:04:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'abb80386-f1da-4043-a595-1c6003c53284' User entered 'No (N)'	(b) (4), (b) (6) System	06 Nov 2020 19:05:28
	System	06 Nov 2020 19:05:28



US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-06T14:04:52', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'abb80386-f1da-4043-a595-1c6003c53284' User entered 'No (N)'	(b) (4), (b) (6) System	06 Nov 2020 19:05:28
	System	06 Nov 2020 19:05:28

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-06T14:05:06', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'abb80386-f1da-4043-a595-1c6003c53284' User entered 'Yes (Y)'	(b) (4), (b) (6) System	06 Nov 2020 19:05:28
	System	06 Nov 2020 19:05:28

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-06T14:05:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'abb80386-f1da-4043-a595-1c6003c53284'	(b) (4), (b) (6)	06 Nov 2020 19:05:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Nov 2020 19:05:28

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-06T14:05:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'abb80386-f1da-4043-a595-1c6003c53284' User entered '06 Nov 2020 14:05:20'	(b) (4), (b) (6) System	06 Nov 2020 19:05:28
	System	06 Nov 2020 19:05:28

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 20:04:05

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 99'	System	08 Aug 2020 20:04:05

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-15T16:28:41', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'b267534b-0337-421f-995a-5164034d89d1' User entered 'No (N)'	(b) (4), (b) (6) System	15 Nov 2020 21:28:51
	System	15 Nov 2020 21:28:51



US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-15T16:28:45', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'b267534b-0337-421f-995a-5164034d89d1'	(b) (4), (b) (6)	15 Nov 2020 21:28:51
User entered 'No (N)'	System	15 Nov 2020 21:28:51

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-15T16:28:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'b267534b-0337-421f-995a-5164034d89d1' User entered '15 Nov 2020 16:28:49'	(b) (4), (b) (6) System	15 Nov 2020 21:28:51
	System	15 Nov 2020 21:28:51

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:17
	(b) (4), (b) (6)	
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14
Data entry locked.	System	08 Aug 2020 20:04:05
User entered 'Day 106'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

US3242051

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:53

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 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 20:04:05

**US3242051**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:43:14
Data entry locked.	System	08 Aug 2020 20:04:05
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 20:04:05



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-19T17:03:03', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3d6563b7-7595-4fb4-9936-5466dfa6ec40'	System	19 Nov 2020 22:03:14
User entered 'No (N)'	System	19 Nov 2020 22:03:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-19T17:03:08', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3d6563b7-7595-4fb4-9936-5466dfa6ec40' User entered 'No (N)'	System	19 Nov 2020 22:03:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-19T17:03:11', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '3d6563b7-7595-4fb4-9936-5466dfa6ec40' User entered '19 Nov 2020 17:03:11'	System	19 Nov 2020 22:03:14
	System	19 Nov 2020 22:03:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-24T14:03:56', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd1b4e7db-b419-47cd-9d73-873829e03dc8'	System	24 Nov 2020 19:04:08
User entered 'No (N)'	System	24 Nov 2020 19:04:08



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-24T14:04:01', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd1b4e7db-b419-47cd-9d73-873829e03dc8'	System	24 Nov 2020 19:04:08
User entered 'No (N)'	System	24 Nov 2020 19:04:08

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-11-24T14:04:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'd1b4e7db-b419-47cd-9d73-873829e03dc8' User entered '24 Nov 2020 14:04:05'	System	24 Nov 2020 19:04:08
	System	24 Nov 2020 19:04:08

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-01T08:15:38', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e573cb37-9f38-403e-b287-f4a18c5e2c0e'	System	01 Dec 2020 13:15:51
User entered 'No (N)'	System	01 Dec 2020 13:15:51

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-01T08:15:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e573cb37-9f38-403e-b287-f4a18c5e2c0e' User entered 'No (N)'	System	01 Dec 2020 13:15:51
	System	01 Dec 2020 13:15:51

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-01T08:15:47', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e573cb37-9f38-403e-b287-f4a18c5e2c0e' User entered '01 Dec 2020 08:15:47'	System	01 Dec 2020 13:15:51
	System	01 Dec 2020 13:15:51



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-08T14:32:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0dbdc999-e22c-4b04-8d9e-b0576f4c45d7' User entered 'No (N)'	System	08 Dec 2020 19:33:10
	System	08 Dec 2020 19:33:10

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-08T14:33:04', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0dbdc999-e22c-4b04-8d9e-b0576f4c45d7' User entered 'No (N)'	System	08 Dec 2020 19:33:10
	System	08 Dec 2020 19:33:10

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-08T14:33:07', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0dbdc999-e22c-4b04-8d9e-b0576f4c45d7' User entered '08 Dec 2020 14:33:07'	System	08 Dec 2020 19:33:10
	System	08 Dec 2020 19:33:10

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-15T09:16:16', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '243a44b2-3926-427c-95b8-ed1a10f5309c' User entered 'No (N)'	System	15 Dec 2020 14:16:30
	System	15 Dec 2020 14:16:30

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-15T09:16:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '243a44b2-3926-427c-95b8-ed1a10f5309c' User entered 'No (N)'	System	15 Dec 2020 14:16:30
	System	15 Dec 2020 14:16:30

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-15T09:16:24', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '243a44b2-3926-427c-95b8-ed1a10f5309c' User entered '15 Dec 2020 09:16:24'	System	15 Dec 2020 14:16:30
	System	15 Dec 2020 14:16:30

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-21T15:28:14', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8ffcacff-5117-4337-9f07-352c6c1f7ebc'	System	21 Dec 2020 20:28:23
User entered 'No (N)'	System	21 Dec 2020 20:28:23



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-21T15:28:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8ffcacff-5117-4337-9f07-352c6c1f7ebc'	System	21 Dec 2020 20:28:23
User entered 'No (N)'	System	21 Dec 2020 20:28:23

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-21T15:28:20', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8ffcacff-5117-4337-9f07-352c6c1f7ebc' User entered '21 Dec 2020 15:28:20'	System	21 Dec 2020 20:28:23
	System	21 Dec 2020 20:28:23

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-28T18:14:35', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'ee66b296-d0ad-4fe9-9cd0-9bb16815021d' User entered 'No (N)'	System	28 Dec 2020 23:14:45
	System	28 Dec 2020 23:14:45

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-28T18:14:38', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'ee66b296-d0ad-4fe9-9cd0-9bb16815021d' User entered 'No (N)'	System	28 Dec 2020 23:14:45

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2020-12-28T18:14:43', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'ee66b296-d0ad-4fe9-9cd0-9bb16815021d' User entered '28 Dec 2020 18:14:43'	System	28 Dec 2020 23:14:45
	System	28 Dec 2020 23:14:45



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-05T09:56:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7e924a75-b6bf-4d80-9907-65c40eb90503'	System	05 Jan 2021 14:57:02
User entered 'No (N)'	System	05 Jan 2021 14:57:02

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-05T09:56:53', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7e924a75-b6bf-4d80-9907-65c40eb90503'	System	05 Jan 2021 14:57:02
User entered 'No (N)'	System	05 Jan 2021 14:57:02

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-05T09:56:59', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '7e924a75-b6bf-4d80-9907-65c40eb90503' User entered '05 Jan 2021 09:56:59'	System	05 Jan 2021 14:57:02
	System	05 Jan 2021 14:57:02

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-11T12:11:43', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8b1192d4-a908-44d2-aeb7-3ee0b949006f' User entered 'No (N)'	System	11 Jan 2021 17:11:52
	System	11 Jan 2021 17:11:52

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-11T12:11:46', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8b1192d4-a908-44d2-aeb7-3ee0b949006f' User entered 'No (N)'	System	11 Jan 2021 17:11:52
	System	11 Jan 2021 17:11:52

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-11T12:11:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8b1192d4-a908-44d2-aeb7-3ee0b949006f' User entered '11 Jan 2021 12:11:49'	System	11 Jan 2021 17:11:52
	System	11 Jan 2021 17:11:52

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-19T09:34:05', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c9fafbe8-0518-4b9d-8a4b-71ad3e4bdfec' User entered 'No (N)'	System	19 Jan 2021 14:34:15
	System	19 Jan 2021 14:34:15



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-19T09:34:09', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c9fafbe8-0518-4b9d-8a4b-71ad3e4bdfec'	System	19 Jan 2021 14:34:15
User entered 'No (N)'	System	19 Jan 2021 14:34:15

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-19T09:34:12', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'c9fafbe8-0518-4b9d-8a4b-71ad3e4bdfec' User entered '19 Jan 2021 09:34:12'	System	19 Jan 2021 14:34:15
	System	19 Jan 2021 14:34:15

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-25T17:26:42', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e030a9d2-d1af-4bfa-b86d-95c947931cdf'	System	25 Jan 2021 22:26:53
User entered 'No (N)'	System	25 Jan 2021 22:26:53

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-25T17:26:45', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e030a9d2-d1af-4bfa-b86d-95c947931cdf' User entered 'No (N)'	System	25 Jan 2021 22:26:53
	System	25 Jan 2021 22:26:53

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-01-25T17:26:50', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e030a9d2-d1af-4bfa-b86d-95c947931cdf' User entered '25 Jan 2021 17:26:50'	System	25 Jan 2021 22:26:53
	System	25 Jan 2021 22:26:53



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-01T07:58:19', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '82d37212-e5e6-4d5c-9efd-d0d4cd5889f1' User entered 'No (N)'	System	01 Feb 2021 12:58:30
	System	01 Feb 2021 12:58:30

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-01T07:58:23', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '82d37212-e5e6-4d5c-9efd-d0d4cd5889f1' User entered 'No (N)'	System	01 Feb 2021 12:58:30

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-01T07:58:27', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '82d37212-e5e6-4d5c-9efd-d0d4cd5889f1' User entered '01 Feb 2021 07:58:27'	System	01 Feb 2021 12:58:30
	System	01 Feb 2021 12:58:30

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-08T10:35:41', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9a836db1-adfa-4e91-bbe4-94810928821d' User entered 'No (N)'	System	08 Feb 2021 15:35:51
	System	08 Feb 2021 15:35:51

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-08T10:35:43', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9a836db1-adfa-4e91-bbe4-94810928821d' User entered 'No (N)'	System	08 Feb 2021 15:35:51
	System	08 Feb 2021 15:35:51

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-08T10:35:49', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '9a836db1-adfa-4e91-bbe4-94810928821d' User entered '08 Feb 2021 10:35:49'	System	08 Feb 2021 15:35:51
	System	08 Feb 2021 15:35:51

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-16T09:17:14', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8f9bc651-b4c3-46ce-b210-5788d672ea6d' User entered 'No (N)'	System	16 Feb 2021 14:17:23
	System	16 Feb 2021 14:17:23



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-16T09:17:17', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8f9bc651-b4c3-46ce-b210-5788d672ea6d' User entered 'No (N)'	System	16 Feb 2021 14:17:23

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-16T09:17:21', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8f9bc651-b4c3-46ce-b210-5788d672ea6d' User entered '16 Feb 2021 09:17:21'	System	16 Feb 2021 14:17:23
	System	16 Feb 2021 14:17:23

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-24T11:24:52-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f05feb19-1487-490d-bf00-7c5d55455971' User entered 'No (N)'	System	24 Feb 2021 16:25:06
	System	24 Feb 2021 16:25:06

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-24T11:24:55-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f05feb19-1487-490d-bf00-7c5d55455971' User entered 'No (N)'	System	24 Feb 2021 16:25:06
	System	24 Feb 2021 16:25:06

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-02-24T11:24:59-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f05feb19-1487-490d-bf00-7c5d55455971' User entered '24 Feb 2021 16:24:59'	System	24 Feb 2021 16:25:06
	System	24 Feb 2021 16:25:06



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-01T12:26:13-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0ebfbd57-62d5-4dc3-a87a-53ffbd1a7410'	System	01 Mar 2021 17:32:52
User entered 'No (N)'	System	01 Mar 2021 17:32:52

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-01T12:26:15-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0ebfbd57-62d5-4dc3-a87a-53ffbd1a7410'	System	01 Mar 2021 17:32:52
User entered 'No (N)'	System	01 Mar 2021 17:32:52

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-01T12:26:19-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '0ebfbd57-62d5-4dc3-a87a-53ffbd1a7410'	System	01 Mar 2021 17:32:52
User entered '01 Mar 2021 12:26:19'	System	01 Mar 2021 17:32:52

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-08T07:26:33-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '638c899c-f3c0-47a1-96d0-673b54c12b75'	System	08 Mar 2021 12:26:45
User entered 'No (N)'	System	08 Mar 2021 12:26:45

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-08T07:26:39-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '638c899c-f3c0-47a1-96d0-673b54c12b75'	System	08 Mar 2021 12:26:45
User entered 'No (N)'	System	08 Mar 2021 12:26:45

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-08T07:26:43-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '638c899c-f3c0-47a1-96d0-673b54c12b75' User entered '08 Mar 2021 07:26:43'	System	08 Mar 2021 12:26:45
	System	08 Mar 2021 12:26:45

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-17T12:02:08-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '823bd792-add4-4c35-a7dc-26b7a461c433'	System	17 Mar 2021 16:06:39
User entered 'No (N)'	System	17 Mar 2021 16:06:39



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-17T12:02:14-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '823bd792-add4-4c35-a7dc-26b7a461c433'	System	17 Mar 2021 16:06:39
User entered 'No (N)'	System	17 Mar 2021 16:06:39

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-17T12:02:17-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '823bd792-add4-4c35-a7dc-26b7a461c433'	System	17 Mar 2021 16:06:39
User entered '17 Mar 2021 12:02:17'	System	17 Mar 2021 16:06:39

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-25T17:59:12-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8012eba6-f6d2-492d-8112-b7baeb98d2c4'	System	25 Mar 2021 21:59:24
User entered 'No (N)'	System	25 Mar 2021 21:59:24

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-25T17:59:17-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8012eba6-f6d2-492d-8112-b7baeb98d2c4'	System	25 Mar 2021 21:59:24
User entered 'No (N)'	System	25 Mar 2021 21:59:24

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-25T17:59:21-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '8012eba6-f6d2-492d-8112-b7baeb98d2c4' User entered '25 Mar 2021 17:59:21'	System	25 Mar 2021 21:59:24
	System	25 Mar 2021 21:59:24



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-30T15:28:27-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f8bf680e-6994-4c53-8a91-1ea7fe3a817a'	System	30 Mar 2021 19:28:38
User entered 'No (N)'	System	30 Mar 2021 19:28:38

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-30T15:28:29-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f8bf680e-6994-4c53-8a91-1ea7fe3a817a'	System	30 Mar 2021 19:28:38
User entered 'No (N)'	System	30 Mar 2021 19:28:38

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-30T15:28:33-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'f8bf680e-6994-4c53-8a91-1ea7fe3a817a' User entered '30 Mar 2021 15:28:33'	System	30 Mar 2021 19:28:38
	System	30 Mar 2021 19:28:38

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-05T07:42:13-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5e24ca02-213e-49ec-a2a6-dc9ecc0bb52e' User entered 'No (N)'	System	05 Apr 2021 11:42:20
	System	05 Apr 2021 11:42:20

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-05T07:42:15-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5e24ca02-213e-49ec-a2a6-dc9ecc0bb52e' User entered 'No (N)'	System	05 Apr 2021 11:42:20
	System	05 Apr 2021 11:42:20

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-05T07:42:17-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '5e24ca02-213e-49ec-a2a6-dc9ecc0bb52e' User entered '05 Apr 2021 07:42:17'	System	05 Apr 2021 11:42:20
	System	05 Apr 2021 11:42:20

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-14T09:16:39-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dee327c3-e50f-43e1-a5fd-9447cb605519'	System	14 Apr 2021 17:33:39
User entered 'No (N)'	System	14 Apr 2021 17:33:39



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-14T09:16:41-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dee327c3-e50f-43e1-a5fd-9447cb605519'	System	14 Apr 2021 17:33:39
User entered 'No (N)'	System	14 Apr 2021 17:33:39

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-14T09:16:44-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'dee327c3-e50f-43e1-a5fd-9447cb605519'	System	14 Apr 2021 17:33:39
User entered '14 Apr 2021 09:16:44'	System	14 Apr 2021 17:33:39

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-19T11:12:02-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1b70a492-a809-46df-b1a0-1c4ee0bf5d9b'	System	19 Apr 2021 15:12:11
User entered 'No (N)'	System	19 Apr 2021 15:12:11

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-19T11:12:04-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1b70a492-a809-46df-b1a0-1c4ee0bf5d9b'	System	19 Apr 2021 15:12:11
User entered 'No (N)'	System	19 Apr 2021 15:12:11

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-19T11:12:07-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '1b70a492-a809-46df-b1a0-1c4ee0bf5d9b' User entered '19 Apr 2021 11:12:07'	System	19 Apr 2021 15:12:11
	System	19 Apr 2021 15:12:11



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-27T08:41:53-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '949ffc7f-b6cf-4710-99a5-bb30aa893977'	System	29 Apr 2021 00:12:29
User entered 'No (N)'	System	29 Apr 2021 00:12:29

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-27T08:41:57-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '949ffc7f-b6cf-4710-99a5-bb30aa893977'	System	29 Apr 2021 00:12:29
User entered 'No (N)'	System	29 Apr 2021 00:12:29

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-04-27T08:42:01-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '949ffc7f-b6cf-4710-99a5-bb30aa893977'	System	29 Apr 2021 00:12:29
User entered '27 Apr 2021 08:42:01'	System	29 Apr 2021 00:12:29

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-05-03T18:04:21-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '2b98251c-cbbd-4724-96b0-f765e249000d'	System	03 May 2021 22:11:22
User entered 'No (N)'	System	03 May 2021 22:11:22

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[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 (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-05-03T18:04:25-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '2b98251c-cbbd-4724-96b0-f765e249000d'	System	03 May 2021 22:11:22
User entered 'No (N)'	System	03 May 2021 22:11:22

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-05-03T18:04:28-04:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: '2b98251c-cbbd-4724-96b0-f765e249000d'	System	03 May 2021 22:11:22
User entered '03 May 2021 18:04:28'	System	03 May 2021 22:11:22

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:43:14



**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:43:14

**US3242051**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:43:14
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:43:14

US3242051

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:11:53

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)	25 Apr 2021 07:41:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-01T12:26:26-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e41e6c72-a7de-4233-a275-d57e0c85a41f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	01 Mar 2021 17:33:17
	System	01 Mar 2021 17:33:17



US3242051

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:11:53**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-01T12:26:35-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e41e6c72-a7de-4233-a275-d57e0c85a41f' User entered 'No (N)'	(b) (4), (b) (6) System	01 Mar 2021 17:33:17
	System	01 Mar 2021 17:33:17

**US3242051**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00BC45D9-C327-4354-84A4-32074C2160C7)', Time: '2021-03-01T12:26:38-05:00', User OID: 'PatientReportedOutcome (US3242051)', ODM File OID: 'e41e6c72-a7de-4233-a275-d57e0c85a41f' User entered '01 Mar 2021 12:26:38'	(b) (4), (b) (6) System	01 Mar 2021 17:33:17
	System	01 Mar 2021 17:33:17

**US3242051**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Nov 2020 15:23:59
	(b) (4)	

US3242051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:02
	(b) (4), (b) (6)	
User entered '9 Nov 2020'	Erynn McKinley (b) (4)	10 Nov 2020 15:23:59
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:02
	(b) (4), (b) (6)	
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	10 Nov 2020 15:23:59
	(b) (4)	

US3242051

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:23:59
	(b) (4)	

US3242051

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Nov 2020 15:24:04
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:54:24
User entered 'I'	System	10 Nov 2020 15:24:04



**US3242051**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Dec 2020 16:02:07
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '8 Dec 2020'	Erynn McKinley (b) (4)	08 Dec 2020 16:02:07
	(b) (4)	

US3242051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	08 Dec 2020 16:02:07
	(b) (4)	

US3242051

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Erynn McKinley (b) (4)	08 Dec 2020 16:02:07
	(b) (4)	

US3242051

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Dec 2020 16:02:11
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered 'I'	(b) (4), (b) (6) System	08 Dec 2020 16:02:11

**US3242051**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Jan 2021 15:31:28
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '6 Jan 2021'	Erynn McKinley (b) (4)	06 Jan 2021 15:31:28
	(b) (4)	



US3242051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	06 Jan 2021 15:31:28
	(b) (4)	

US3242051

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Erynn McKinley (b) (4)	06 Jan 2021 15:31:28
	(b) (4)	

US3242051

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Jan 2021 15:31:30
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered 'I'	(b) (4), (b) (6) System	06 Jan 2021 15:31:30

**US3242051**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Feb 2021 16:59:55
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '8 Feb 2021'	Erynn McKinley (b) (4)	08 Feb 2021 16:59:55
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	08 Feb 2021 16:59:55
	(b) (4)	

US3242051

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Erynn McKinley (b) (4)	08 Feb 2021 16:59:55
	(b) (4)	



US3242051

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Feb 2021 17:00:04
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered 'I'	(b) (4), (b) (6) System	08 Feb 2021 17:00:04

US3242051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	16 Mar 2021 20:44:46
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered '16 Mar 2021'	Erynn McKinley (b) (4)	16 Mar 2021 20:44:46
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:53

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 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	16 Mar 2021 20:44:46
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered 'VISIT4'	(b) (4), (b) (6) System	16 Mar 2021 20:44:46

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	



US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:10:17

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:10:17

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	



US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:10:17

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:10:17

US3242051

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:40:26
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:10:17
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:10:17

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 15:05:07

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 15:05:07

US3242051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'No (N)'	Erynn McKinley (b) (4)	16 Mar 2021 20:44:54
	(b) (4)	



US3242051

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4)	16 Mar 2021 20:44:54
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	16 Mar 2021 20:45:04
	(b) (4)	

US3242051

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered '16 Mar 2021'	Erynn McKinley (b) (4)	16 Mar 2021 20:45:04
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered '16:10'	Erynn McKinley (b) (4)	16 Mar 2021 20:45:04
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered '16 Mar 2021 16:10'	(b) (4), (b) (6) System	16 Mar 2021 20:45:04

US3242051

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	16 Mar 2021 20:45:06
	(b) (4)	

**US3242051**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:05:07
User entered 'I'	(b) (4), (b) (6) System	16 Mar 2021 20:45:06

**US3242051**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:54:58
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	06 Apr 2021 14:09:13
	(b) (4)	



**US3242051**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:54:58
User entered '06 Apr 2021'	Erynn McKinley (b) (4) (b) (4)	06 Apr 2021 14:09:13

US3242051

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:54:58
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	06 Apr 2021 14:09:13

US3242051

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Apr 2021 20:54:58
User entered empty.	Erynn McKinley (b) (4)	06 Apr 2021 14:09:13
	(b) (4)	

**US3242051**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Apr 2021 20:54:58
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	06 Apr 2021 14:09:17

**US3242051**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:46:22
User entered 'I'	(b) (4), (b) (6) System	06 Apr 2021 14:09:17

**US3242051**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:38

**US3242051**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:38

**US3242051**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:38



**US3242051**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	20 Jan 2021 22:56:38

US3242051

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55

**US3242051**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:11:53**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:56:44
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:31:03

US3242051

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55

**US3242051**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:11:53**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 15:56:44
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 03:31:03

US3242051

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55

US3242051

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Placebo (Placebo)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55

**US3242051**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:11:53**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Placebo (Placebo)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55



US3242051

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Placebo (Placebo)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55

US3242051

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

Form: Unblinding

Generated On: 09 Jun 2021 16:11:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:56:55

**US3242051**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:11:53**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '1'	(b) (4), (b) (6) System	20 Jan 2021 22:56:55

**US3242051**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'I'	(b) (4), (b) (6) System	20 Jan 2021 22:56:55

US3242051

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:11:53**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User entered empty.	System	20 Jan 2021 22:58:19
DataPoint set to visible.	System	20 Jan 2021 22:56:55

US3242051

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19



US3242051

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:11:53**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:58:19
DataPoint set to visible.	System	20 Jan 2021 22:56:55

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '17:55'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '20 Jan 2021 17:55'	(b) (4), (b) (6) System	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '97.4' F	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19



**US3242051**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '82'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'bpm'	(b) (4), (b) (6) System	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '16'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '128'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	20 Jan 2021 22:58:19



US3242051

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '78'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

US3242051

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:19

**US3242051**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:58:19
DataPoint set to visible.	System	20 Jan 2021 22:56:55

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48



US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '18:47'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

**US3242051**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '20 Jan 2021 18:47'	(b) (4), (b) (6) System	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '98.1' F	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '76'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

**US3242051**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'bpm'	(b) (4), (b) (6) System	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '16'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48



US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '132'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

**US3242051**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '78'	Donna Toepfer (b) (4)	20 Jan 2021 23:49:48

US3242051

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	20 Jan 2021 23:49:48

US3242051

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	20 Jan 2021 22:58:34

US3242051

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	20 Jan 2021 22:58:34

US3242051

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 23:38:23



**US3242051**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	20 Jan 2021 23:38:23

US3242051

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

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)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	20 Jan 2021 23:38:23

**US3242051**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	20 Jan 2021 23:38:23
DataPoint set to visible.	System	20 Jan 2021 22:56:55

US3242051

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 23:38:23

US3242051

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '18:17'	Donna Toepfer (b) (4)	20 Jan 2021 23:38:23

**US3242051**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '20 Jan 2021 18:17'	(b) (4), (b) (6) System	20 Jan 2021 23:38:23

US3242051

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	20 Jan 2021 23:38:23

US3242051

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

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'ONCE'	(b) (4), (b) (6) System	20 Jan 2021 23:38:23



**US3242051**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	20 Jan 2021 23:38:23

US3242051

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:19

US3242051

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:19

**US3242051**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '17:33'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:19

**US3242051**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '20 Jan 2021 17:33'	(b) (4), (b) (6) System	20 Jan 2021 22:57:19

US3242051

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:33

**US3242051**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '20 Jan 2021'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:33

**US3242051**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:11:53**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '15:57'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:33



**US3242051**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:11:53**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '20 Jan 2021 15:57'	(b) (4), (b) (6) System	20 Jan 2021 22:57:33

US3242051

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

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	20 Jan 2021 22:57:37

**US3242051**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'I'	(b) (4), (b) (6) System	20 Jan 2021 22:57:37

**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	27 Jan 2021 16:26:27

**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '27 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	27 Jan 2021 16:26:27

**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	27 Jan 2021 16:26:27

**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Erynn McKinley (b) (4) (b) (4)	27 Jan 2021 16:26:27

**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	27 Jan 2021 16:26:58



**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'I'	(b) (4), (b) (6) System	27 Jan 2021 16:26:58

**US3242051**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User entered 'I'	System	27 Jan 2021 16:26:58
DataPoint set to visible.	System	27 Jan 2021 16:26:58

**US3242051**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:08:33

**US3242051**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '16 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:08:33

**US3242051**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:08:33

**US3242051**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'OLD29'	(b) (4), (b) (6) System	16 Feb 2021 22:08:33

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36



**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '16 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '15:55'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '16 Feb 2021 15:55'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '97.5' F	Erynn McKinley (b) (4)	16 Feb 2021 22:09:36
	(b) (4)	

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered empty.	Erynn McKinley (b) (4)	16 Feb 2021 22:09:36
	(b) (4)	

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '68'	Erynn McKinley (b) (4)	16 Feb 2021 22:09:36
	(b) (4)	

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'bpm'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36



US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '16'	Erynn McKinley (b) (4)	16 Feb 2021 22:09:36
	(b) (4)	

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '130'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '72'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	16 Feb 2021 22:09:36
	(b) (4)	



**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '16 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '17:03'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '16 Feb 2021 17:03'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '97.6' F	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Oral (Oral)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '64'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'bpm'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36



US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '18'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

US3242051

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '134'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '76'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:09:36

**US3242051**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:11:53**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:41

**US3242051**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:11:53**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered empty.	Erynn McKinley (b) (4)	16 Feb 2021 22:09:41
	(b) (4)	



**US3242051**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:52

**US3242051**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:52

US3242051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

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)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:52

US3242051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'mRNA-1273'	(b) (4), (b) (6)	16 Feb 2021 22:09:52
DataPoint set to visible.	System	27 Jan 2021 16:26:58

US3242051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '16 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:52

US3242051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered '16:29'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:52

**US3242051**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '16 Feb 2021 16:29'	(b) (4), (b) (6) System	16 Feb 2021 22:09:52

**US3242051**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:52



**US3242051**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:11:53**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'ONCE'	(b) (4), (b) (6) System	16 Feb 2021 22:09:52

US3242051

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	16 Feb 2021 22:09:52

US3242051

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Feb 2021 17:19:37
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	16 Feb 2021 22:09:56

**US3242051**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'I'	(b) (4), (b) (6) System	16 Feb 2021 22:09:56

**US3242051**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:01:43
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	24 Feb 2021 21:13:47

**US3242051**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:01:43
User entered '24 Feb 2021'	Erynn McKinley (b) (4) (b) (4)	24 Feb 2021 21:13:47

**US3242051**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:11:53**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:01:43
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4) (b) (4)	24 Feb 2021 21:13:47

US3242051

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:01:43
User entered empty.	Erynn McKinley (b) (4) (b) (4)	24 Feb 2021 21:13:47



US3242051

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:01:43
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	24 Feb 2021 21:13:50

**US3242051**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:11:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'I'	(b) (4), (b) (6) System	24 Feb 2021 21:13:50

**US3242051**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:27

**US3242051**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered '16 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:27

**US3242051**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:27

**US3242051**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:11:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered 'OLD57'	(b) (4), (b) (6) System	16 Mar 2021 20:45:27

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35



**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6) System	16 Mar 2021 20:45:35

US3242051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

US3242051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6) System	16 Mar 2021 20:45:35

US3242051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35



**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6) System	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6) System	16 Mar 2021 20:45:35

US3242051

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered empty.	(b) (4), (b) (6) System	16 Mar 2021 20:45:35

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 09:51:19

**US3242051**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:11:53**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 09:51:19

**US3242051**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:11:53**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:40



**US3242051**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:11:53**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered empty.	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:40

**US3242051**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered 'Yes (Y)'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:51

**US3242051**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered '16 Mar 2021'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:51

**US3242051**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	17 Mar 2021 12:24:33
User entered '16:10'	Erynn McKinley (b) (4) (b) (4)	16 Mar 2021 20:45:51

**US3242051**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:11:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:51:19
User entered '16 Mar 2021 16:10'	(b) (4), (b) (6) System	16 Mar 2021 20:45:51

US3242051

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:11:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:35:54
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:53
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:21:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	28 Sep 2020 15:53:31
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 19:24:19

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30

US3242051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Per CDM: Please verify if this pertains to #6 EAR INFECTION in the Con Med eCRF? If yes, note that Con Med 'indication' does not match the corresponding AE record? Please review and reconcile Con Med and AE as appropriate else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:27:36
Query 'Per CDM: Please verify if this pertains to #6 EAR INFECTION in the Con Med eCRF? If yes, note that Con Med 'indication' does not match the corresponding AE record? Please review and reconcile Con Med and AE as appropriate else clarify.' answered with 'updated source' (Site from DM).	Donna Toepfer (b) (4)	20 Nov 2020 14:19:42
User opened query 'Per CDM: Please verify if this pertains to #6 EAR INFECTION in the Con Med eCRF? If yes, note that Con Med 'indication' does not match the corresponding AE record? Please review and reconcile Con Med and AE as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:27:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media acute, LLT: Otitis media acute - version MedDRA\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	28 Sep 2020 15:56:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:56:41
Data point term sent to Coder	System	28 Sep 2020 15:55:40
User entered 'Acute Otitis Media, right'	Erynn McKinley (b) (4) (b) (4)	28 Sep 2020 15:54:56



**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '19 Sep 2020'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User entered empty.	(b) (4), (b) (6) System	28 Sep 2020 15:54:56

US3242051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:13:50
	(b) (4), (b) (6)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:06:42
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:06:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

US3242051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:13:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:06:42
User entered '02 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:06:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	



**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User entered empty.	(b) (4), (b) (6) System	28 Sep 2020 15:54:56

US3242051

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:32:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:32:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)' Donna Toepfer reason for change: Data Entry Error	(b) (4)	28 Sep 2020 20:32:34
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:54:56
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'No (N)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	



**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:32:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:32:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	28 Sep 2020 20:32:34
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:54:56
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:32:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:32:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	28 Sep 2020 20:32:34
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 15:54:56
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'None (NONE)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User signature succeeded.	(b) (4), (b) (6)	
	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 12:32:34
	(b) (4), (b) (6)	
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify. ' (Site from DM).	Donna Toepfer (b) (4)	12 Oct 2020 13:08:39
User entered 'I'	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	12 Oct 2020 04:57:38
	(b) (4), (b) (6)	
	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:14:02
	(b) (4), (b) (6)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:06:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Donna Toepfer (b) (4)	17 Nov 2020 20:06:42
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	28 Sep 2020 15:54:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User entered '0'	(b) (4), (b) (6) System	28 Sep 2020 15:54:56



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:41:30
User entered '1'	(b) (4), (b) (6) System	28 Sep 2020 15:54:56

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 00:41:30

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 15:14:18
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:27
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	11 Nov 2020 20:53:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Trimalleolar fracture - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 15:04:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 15:04:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:14:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Malleolar fracture - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 21:03:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 21:03:01
Data point term sent to Coder	System	17 Nov 2020 20:08:41
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
Coding entries removed.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
User entered 'Trimalleolar Ankle Fracture, right' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Broken ankle - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 15:28:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 15:28:37
Data point term sent to Coder	System	10 Nov 2020 15:27:43
User entered 'Broken Right Ankle'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered 'No (N)'	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	10 Nov 2020 15:27:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'No (N)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '1 Nov 2020'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 15:27:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:15:21
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Un-verified.	(b) (4) Donna Toepfer (b) (4)	12 Apr 2021 19:22:44
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 19:22:44
User closed query 'Per CDM: Please review/provide current update if AE has 'resolved' or, is still 'ongoing' as response states' confirm with subject on 1/27/2020, still ongoing'? Thank you' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 10:18:01
Query 'Per CDM: Please review/provide current update if AE has 'resolved' or, is still 'ongoing' as response states' confirm with subject on 1/27/2020, still ongoing'? Thank you' answered with 'Ongoing as of contact with subject on 08Feb2021' (Site from DM).	Donna Toepfer (b) (4)	10 Feb 2021 14:48:51
User opened query 'Per CDM: Please review/provide current update if AE has 'resolved' or, is still 'ongoing' as response states' confirm with subject on 1/27/2020, still ongoing'? Thank you' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:06:40
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 10:06:40
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'confirm with subject on 1/27/2020, still ongoing' (Site from DM).	Donna Toepfer (b) (4)	30 Jan 2021 15:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:14:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED] Donna Toepfer (b) (4) [REDACTED] [REDACTED]	13 Jan 2021 13:19:35  17 Nov 2020 20:29:06  17 Nov 2020 20:08:06
DataPoint Un-verified.	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	17 Nov 2020 20:08:06
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	17 Nov 2020 20:08:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered 'Yes (Y)'	Erynn McKinley (b) (4) [REDACTED]	10 Nov 2020 15:27:01

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:15:19
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Un-verified.	(b) (4) Donna Toepfer (b) (4)	12 Apr 2021 19:22:44
User entered '31 Mar 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Apr 2021 19:22:44
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:14:18
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.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 14:21:17
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)	24 Nov 2020 14:20:52
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:29:06
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 20:08:25
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	17 Nov 2020 20:08:25
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	17 Nov 2020 20:08:06
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
User entered '05 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06

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**Folder: Adverse Events**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:37:40
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 'ongoing at this time' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 14:50:39
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)	20 Nov 2020 19:24:55
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered empty.	Erynn McKinley (b) (4) (b) (4)	10 Nov 2020 15:27:01

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:18:03
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)	03 Dec 2020 21:57:13
User entered empty.	System	10 Nov 2020 15:27:01



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
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) (4), (b) (6)	23 Nov 2020 20:53:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:22:02
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 'updated' (Site from System).	Donna Toepfer (b) (4)	10 Nov 2020 15:46:07
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	10 Nov 2020 15:27:01
User entered 'I'	Erynn McKinley (b) (4) (b) (4)	10 Nov 2020 15:27:01

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '2 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	10 Nov 2020 15:29:30
	(b) (4)	
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 15:14:18
	(b) (4), (b) (6)	
User closed query 'PV Query: Please clarify the discharge date: 04 Nov 2020 or 05 Nov 2020. Event description states that the subject was released on 04 Nov 2020 but the hospital discharge date field has 05 Nov 2020 as the discharge date.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:37:45
Query 'PV Query: Please clarify the discharge date: 04 Nov 2020 or 05 Nov 2020. Event description states that the subject was released on 04 Nov 2020 but the hospital discharge date field has 05 Nov 2020 as the discharge date.' answered with 'updated note per med records' (Site from Safety).	Donna Toepfer (b) (4)	24 Nov 2020 15:38:13
User opened query 'PV Query: Please clarify the discharge date: 04 Nov 2020 or 05 Nov 2020. Event description states that the subject was released on 04 Nov 2020 but the hospital discharge date field has 05 Nov 2020 as the discharge date.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:22:49
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
User entered '5 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered '4 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	10 Nov 2020 15:29:30
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 15:14:18
	(b) (4), (b) (6)	
User closed query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:37:49
Query 'PV Query: As the last dose of study drug was given on 11 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)	23 Nov 2020 14:53:32
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Nov 2020 14:51:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 14:51:34
User opened query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:25:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered 'None (NONE)'	(b) (4), (b) (6)	
	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	27 Jan 2021 15:14:18
DataPoint Un-verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:08:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
	(b) (4), (b) (6)	
User entered 'I'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:38
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)	13 Apr 2021 17:05:04
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
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)	12 Apr 2021 19:23:03
DataPoint Un-verified.	Donna Toepfer (b) (4)	12 Apr 2021 19:22:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Donna Toepfer (b) (4)	12 Apr 2021 19:22:44
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:14:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 21:57:33
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)	24 Nov 2020 20:37:54
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 'ongoing at this time' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 14:53:41

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:25:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:29:06
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 20:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered empty.	(b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4)	10 Nov 2020 15:27:01

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:01:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 15:14:18
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide any imaging results used to diagnose the fracture in narrative or with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. If this information will not be available, please confirm in your response. If this information will be obtained, please leave query open until information is provided.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:15:14
Query 'PV Query: Please provide any imaging results used to diagnose the fracture in narrative or with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. If this information will not be available, please confirm in your response. If this information will be obtained, please leave query open until information is provided.' answered with 'updated, will send information to safety' (Site from Safety).	Donna Toepfer (b) (4)	22 Jan 2021 16:06:50
User entered 'DURING SAFETY CALL, SUBJECT REPORTED HE BROKE HIS RIGHT ANKLE(SUBJECT STATED HE "ROLLED" HIS ANKLE) ON 01NOV2020 AND WAS ADMITTED TO GRADY MEMORIAL ON 02NOV2020. HAD SURGERY TO REPAIR ON 03NOV2020 AND WAS RELEASED ON 05NOV2020. COVID TEST IN HOSPITAL WAS NEGATIVE. RECORDS HAVE BEEN REQUESTED. RECORDS, RECEIVED, DIAGNOSIS AND DATES UPDATED.	Donna Toepfer (b) (4)	22 Jan 2021 16:05:38
Update 1/6/21: review of xrays post orthopedic appt, states ankle is healing, subject is still in a boot for part of the day and continues Physical therapy.'		
reason for change: Data Entry Error		

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any imaging results used to diagnose the fracture in narrative or with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. If this information will not be available, please confirm in your response. If this information will be obtained, please leave query open until information is provided.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 19:55:46
User closed query 'PV Query: Thank you for providing the discharge summary. Please provide any imaging results used to diagnose the fracture or confirm if they are not available.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 12:38:55
Query 'PV Query: Thank you for providing the discharge summary. Please provide any imaging results used to diagnose the fracture or confirm if they are not available.' answered with 'not available at this time' (Site from Safety).	Donna Toepfer (b) (4)	05 Dec 2020 17:29:39
User opened query 'PV Query: Thank you for providing the discharge summary. Please provide any imaging results used to diagnose the fracture or confirm if they are not available.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 21:56:51
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)	24 Nov 2020 20:38:11
User closed query 'PV Query: Please clarify how the subject broke his ankle.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:38:07
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:38:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:37:58

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[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 'records sent' (Site from Safety).	Donna Toepfer (b) (4)	24 Nov 2020 16:25:43
User entered 'DURING SAFETY CALL, SUBJECT REPORTED HE BROKE HIS RIGHT ANKLE(SUBJECT STATED HE "ROLLED" HIS ANKLE) ON 01NOV2020 AND WAS ADMITTED TO GRADY MEMORIAL ON 02NOV2020. HAD SURGERY TO REPAIR ON 03NOV2020 AND WAS RELEASED ON 05NOV2020. COVID TEST IN HOSPITAL WAS NEGATIVE. RECORDS HAVE BEEN REQUESTED. RECORDS, RECEIVED, DIAGNOSIS AND DATES UPDATED' reason for change: Data Entry Error	Donna Toepfer (b) (4)	24 Nov 2020 15:38:02
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)	24 Nov 2020 14:23:58
User entered 'DURING SAFETY CALL, SUBJECT REPORTED HE BROKE HIS RIGHT ANKLE(SUBJECT STATED HE "ROLLED" HIS ANKLE) ON 01NOV2020 AND WAS ADMITTED TO GRADY MEMORIAL ON 02NOV2020. HAD SURGERY TO REPAIR ON 03NOV2020 AND WAS RELEASED ON 04NOV2020. COVID TEST IN HOSPITAL WAS NEGATIVE. RECORDS HAVE BEEN REQUESTED. RECORDS, RECEIVED, DIAGNOSIS AND DATES UPDATED' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 14:56:48
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'N/A' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 14:56:19



US3242051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DURING SAFETY CALL, SUBJECT REPORTED HE BROKE HIS RIGHT ANKLE(subject stated he "rolled" his ankle ON 01NOV2020 AND WAS ADMITTED TO GRADY MEMORIAL ON 02NOV2020. HAD SURGERY TO REPAIR ON 03NOV2020 AND WAS RELEASED ON 04NOV2020. COVID TEST IN HOSPITAL WAS NEGATIVE. RECORDS HAVE BEEN REQUESTED. RECORDS, RECEIVED, DIAGNOSIS AND DATES UPDATED' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Nov 2020 14:56:11
Query 'PV Query: Please clarify how the subject broke his ankle.' answered with 'subject states he rolled his ankle' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 14:55:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	23 Nov 2020 14:55:12
User opened query 'PV Query: Please clarify how the subject broke his ankle.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:26:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:26:19
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:25:29
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:53

US3242051

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DURING SAFETY CALL, SUBJECT REPORTED HE BROKE HIS RIGHT ANKLE ON 01NOV2020 AND WAS ADMITTED TO GRADY MEMORIAL ON 02NOV2020. HAD SURGERY TO REPAIR ON 03NOV2020 AND WAS RELEASED ON 04NOV2020. COVID TEST IN HOSPITAL WAS NEGATIVE. RECORDS HAVE BEEN REQUESTED. RECORDS, RECEIVED, DIAGNOSIS AND DATES UPDATED' reason for change: Data Entry Error DataPoint Verified.	Donna Toepfer (b) (4)	17 Nov 2020 20:08:53
	(b) (4), (b) (6)	10 Nov 2020 20:22:02
User entered 'During safety call, subject reported he broke his right ankle on 01Nov2020 and was admitted to Grady Memorial on 02Nov2020. Had surgery to repair on 03Nov2020 and was released on 04Nov2020. Covid test in hospital was negative. Records have been requested.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 15:46:01
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 15:29:30
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 15:29:30
User entered 'Serious due to hospitalization' reason for change: Data Entry Error	Erynn McKinley (b) (4)	10 Nov 2020 15:29:30
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 15:27:01
User entered empty.	Erynn McKinley (b) (4)	10 Nov 2020 15:27:01

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 15:27:01

**US3242051**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 15:27:01

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:11:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:35:54
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:22:55
User entered 'Yes (Y)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	08 Aug 2020 20:05:10

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:07:53
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Aug 2020 20:07:53
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Aug 2020 20:06:42
User entered 'Pravastatin'	Donna Toepfer (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4)	08 Aug 2020 20:05:57



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered '40'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'mg (mg)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'once daily (QD)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
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)	10 Aug 2020 17:19:16
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 'value correct per protocol' (Site from System).	Donna Toepfer (b) (4)	08 Aug 2020 20:08:46
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	08 Aug 2020 20:05:57
User entered 'UN UNK 2006'	Donna Toepfer (b) (4)	08 Aug 2020 20:05:57



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered '0'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:05:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:05:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:05:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:05:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 14:35:34
User closed query 'According to source the spelling of this medication should be Trazadone. Please refer to source and correct as indicated.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 14:35:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:22:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:22:44
Query 'According to source the spelling of this medication should be Trazadone. Please refer to source and correct as indicated.' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	10 Nov 2020 21:21:47
Data point term sent to Coder	System	10 Nov 2020 21:21:32
Coding entries removed.	Donna Toepfer (b) (4)	10 Nov 2020 21:21:29
User entered 'TRAZODONe' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 21:21:29
User opened query 'According to source the spelling of this medication should be Trazadone. Please refer to source and correct as indicated.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:24:43
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: TRAZODON - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:09:45



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Aug 2020 20:09:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	08 Aug 2020 20:08:45
User entered 'Trazodon'	Donna Toepfer (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Insomnia'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered '100'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'mg (mg)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'once daily (QD)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of INSOMNIA. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 15:24:25
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of INSOMNIA. Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	17 Sep 2020 14:54:28
User entered 'UN UNK 2015' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Sep 2020 14:54:16
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of INSOMNIA. Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 05:04:49
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)	10 Aug 2020 17:19:02
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 'value correct per protocol' (Site from System).	Donna Toepfer (b) (4)	08 Aug 2020 20:08:41
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	08 Aug 2020 20:07:57
User entered 'UN UNK 2014'	Donna Toepfer (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered '0'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:07:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:07:57



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:07:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:07:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:09:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:09:45
Data point term sent to Coder	System	08 Aug 2020 20:08:45
User entered 'Escitalopram'	Donna Toepfer (b) (4) (b) (4) (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Anxiety'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered '10'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'mg (mg)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'once daily (QD)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
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)	10 Aug 2020 17:18:48
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 'value correct per protocol' (Site from System).	Donna Toepfer (b) (4)	08 Aug 2020 20:08:36
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	08 Aug 2020 20:08:32
User entered 'UN UNK 2005'	Donna Toepfer (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered '0'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	Donna Toepfer (b) (4)  (b) (4)	08 Aug 2020 20:08:32

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:08:32

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:08:32

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:08:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	12 Oct 2020 14:13:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:13:20
Data point term sent to Coder	System	12 Oct 2020 13:08:14
User entered 'Ibuprofen'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Acute Otitis Media, right'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '800'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'mg (mg)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'twice daily (BID)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered empty.	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '22 Sep 2020'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '0'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '02 Oct 2020'	Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:07:46

US3242051

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User entered '2'	(b) (4), (b) (6) System	12 Oct 2020 13:07:46

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User entered '1'	(b) (4), (b) (6) System	12 Oct 2020 13:07:46

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:42
User entered '804 (804)'	System	12 Oct 2020 13:07:46

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	12 Oct 2020 13:14:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 13:14:22
Data point term sent to Coder	System	12 Oct 2020 13:09:15
User entered 'Amoxicillin'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Acute otitis media, right'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '875'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'mg (mg)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered empty.	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '22 Sep 2020'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '0'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '02 Oct 2020'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	12 Oct 2020 13:08:28

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
User entered '2'	(b) (4), (b) (6) System	12 Oct 2020 13:08:28

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
User entered '1'	(b) (4), (b) (6) System	12 Oct 2020 13:08:28

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:53:58
User entered '804 (804)'	System	12 Oct 2020 13:08:28



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIINFECTIVES, PRODUCT: OFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:51:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:51:42
Data point term sent to Coder	System	06 Jan 2021 15:36:05
Coding entries removed.	Erynn McKinley (b) (4)	06 Jan 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIINFECTIVES, PRODUCT: OFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	10 Nov 2020 15:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:42:37
Data point term sent to Coder	System	10 Nov 2020 15:42:14
User entered 'Ofloxacin'	Erynn McKinley (b) (4) (b) (4)	10 Nov 2020 15:41:50

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'No (N)'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Un-verified.	(b) (4) Erynn McKinley (b) (4)	06 Jan 2021 15:35:13
User entered 'ACUTE OTITIS MEDIA, RIGHT'	(b) (4) Erynn McKinley (b) (4)	06 Jan 2021 15:35:13
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Ear Infection'	Erynn McKinley (b) (4) (b) (4)	10 Nov 2020 15:41:50

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '0.3'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'Other (OTHER)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	10 Nov 2020 15:41:50

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '% percent'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'other (OTHER)'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'five times daily'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered 'Otic'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '22 Sep 2020'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:11:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '0'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:11:53**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	10 Nov 2020 15:41:50

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
	(b) (4), (b) (6)	
User entered '2 Oct 2020'	Erynn McKinley (b) (4)	10 Nov 2020 15:41:50
	(b) (4)	

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:03
User entered 'No (N)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	10 Nov 2020 15:41:50

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 15:41:50



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 15:41:50

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:03
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 15:41:50

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
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)	17 Nov 2020 20:12:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:12:51
Data point term sent to Coder	System	17 Nov 2020 20:11:44
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Trimalleolar Ankle Fracture, right'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '500' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	24 Nov 2020 19:34:43
User entered '50'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'twice daily (BID)'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '05 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '0'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 14:53:59
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '30 Dec 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 14:53:59
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:11:33

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
User entered '2'	(b) (4), (b) (6) System	17 Nov 2020 20:11:33

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 20:11:33

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:37
User entered '804 (804)'	(b) (4), (b) (6) System	17 Nov 2020 20:11:33

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:16:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:16:00
Data point term sent to Coder	System	17 Nov 2020 20:13:46
User entered 'Aspirin EC'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Trimalleolar Ankle Fracture, right'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '81'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '05 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 14:54:26
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Jan 2021 14:54:26
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Jan 2021 14:54:20
User entered '23 Dec 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	06 Jan 2021 14:54:20
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:13:28

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 20:13:28

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 20:13:28

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:42
User entered '804 (804)'	System	17 Nov 2020 20:13:28

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:19:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:19:02
Data point term sent to Coder	System	17 Nov 2020 20:14:48
User entered 'Bisacodyl'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Constipation after surgery'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '10'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'once daily (QD)'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (ORAL)'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '05 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '12 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:14:32

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 20:14:32

US3242051

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 20:14:32

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:54:47
User entered '804 (804)'	System	17 Nov 2020 20:14:32



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:45:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:45:02
Data point term sent to Coder	System	17 Nov 2020 20:15:49
User entered 'Ibuprofen'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Trimalleolar Ankle Fracture, right'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '600'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '05 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:15:17

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 20:15:17



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:15:17

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 20:15:17

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:37:01
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 Nov 2020 07:37:01
Data point term sent to Coder	System	17 Nov 2020 20:16:50
User entered 'Oxycodone IR'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Trimalleolar Ankle Fracture, right'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '5'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (ORAL)'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '05 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '12 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	17 Nov 2020 20:16:13



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 20:16:13

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 20:16:13

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 20:16:13

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:44
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 20:16:13

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:53:53
Data point term sent to Coder	System	22 Jan 2021 16:10:55
User entered 'Mobic'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Trimalleolar Ankle fracture, right'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '7.5'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'mg (mg)'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '7 Jan 2021'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:11:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '0'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered empty.	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:27:21
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Jan 2021 16:10:14

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 16:10:14

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 16:10:14

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Jan 2021 16:10:14

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 17:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 17:14:44
Data point term sent to Coder	System	09 Mar 2021 17:13:11
User entered 'Juvederm'	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. Otherwise, clarify ' canceled (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 16:28:44
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 12:01:40
User signature succeeded.	Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'Cosmetic'	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'I'	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'mL (mL)'	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered empty.	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'as needed (PRN)'	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered empty.	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered empty.	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'UN UNK 2015'	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered '0'	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:11:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'UN UNK 2016'	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:27:21
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	11 Mar 2021 00:25:43
User entered 'No (N)'	(b) (4) Erynn McKinley (b) (4) (b) (4)	09 Mar 2021 17:13:05

US3242051

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
User entered empty.	(b) (4), (b) (6) System	09 Mar 2021 17:13:05

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
User entered empty.	(b) (4), (b) (6) System	09 Mar 2021 17:13:05

US3242051

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:55:54
User entered empty.	(b) (4), (b) (6) System	09 Mar 2021 17:13:05



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:13:05
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	20 Apr 2021 10:13:05
Data point term sent to Coder	System	19 Apr 2021 15:05:00
User entered 'Zofran'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'No (N)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Trimalleolar ankle fracture/nausea'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '4'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'mg (mg)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	19 Apr 2021 15:13:37
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	19 Apr 2021 15:13:37
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	19 Apr 2021 15:04:38
User entered 'once (ONCE)'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '02 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	19 Apr 2021 15:13:37
User entered '02 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 15:13:37
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Apr 2021 15:04:38
User entered '02 Nov 2021'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:04:38

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:04:38



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:04:38

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:33
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:04:38

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:03:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:03:04
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 15:06:01
User entered 'Lactated Ringer Bolus'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Trimalleolar ankle fracture(prophylaxis)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '1000'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'mL (mL)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '02 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '02 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00



US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:06:00

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:39
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:06:00

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:04:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:04:41
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 15:08:03
User entered 'NACL'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Trimalleolar ankle fracture, prophylaxis'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '0.9'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Percent'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '02 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '02 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:07:54

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:45
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:07:54

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:00:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:00:56
Data point term sent to Coder	System	19 Apr 2021 15:09:04
User entered 'General Anesthesia'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Trimalleolar ankle fracture, right'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'UNK'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Other (OTHER)'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Unknown'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered empty.	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57



**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '03 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered '03 Nov 2020'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

US3242051

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:08:57

**US3242051**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:06:51
User entered empty.	(b) (4), (b) (6) System	19 Apr 2021 15:08:57



US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:11:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:35:54
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:26:45
User entered 'Yes (Y)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	10 Nov 2020 15:46:21

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:26:59
User entered '03 Nov 2020'	Donna Toepfer (b) (4)  (b) (4)	10 Nov 2020 15:46:50

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	19 Apr 2021 15:15:04
Signature has been broken.	Donna Toepfer (b) (4)	19 Apr 2021 15:15:04
User entered 'ANKLE REPAIR, RIGHT(Small Fragment plate and screws)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Apr 2021 15:15:04
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:26:59
	(b) (4), (b) (6)	
User entered 'Ankle repair, right'	Donna Toepfer (b) (4)	10 Nov 2020 15:46:50

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:26:59
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)  (b) (4)	10 Nov 2020 15:46:50

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	08 Feb 2021 20:09:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 20:26:59
User entered empty.	Donna Toepfer (b) (4)  (b) (4)	10 Nov 2020 15:46:50

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:16
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '02 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:10:17

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:16
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Xray, right ankle'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:10:17

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:16
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:10:17



US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:16
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:10:17

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:21
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '02 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:16

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:21
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Computerized tomography'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:16

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:21
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:16

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:21
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:16

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:25
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '02 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:40

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:25
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'EKG'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:40

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:25
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:40



US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:25
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:11:40

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '02 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:12:30

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Splint, right ankle (pre-surgery)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:12:30

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:12:30

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:12:30

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '03 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:13:00

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Splint, right ankle (post surgery_ '	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:13:00

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:13:00



US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:53:49
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:13:00

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:11:53

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:54:18
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered '02 Nov 2020'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:15:28

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:11:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:54:18
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Sutures'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:15:28

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:11:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:54:18
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered 'Adverse Event (AE)'	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:15:28

US3242051

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:11:53

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:54:18
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:17:43
User entered empty.	(b) (4) Donna Toepfer (b) (4)	19 Apr 2021 15:15:28

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	



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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
	(b) (4), (b) (6)	
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
	(b) (4), (b) (6)	
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
	(b) (4), (b) (6)	
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 16:14:21
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 16:14:19
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:30:48

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	



US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 16:14:21
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 16:14:19
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:30:48

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:11:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '11/Nov/2020 20:53'	System	11 Nov 2020 20:53:51

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:53

**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)	26 Apr 2021 18:55:14
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	



US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:21
	(b) (4), (b) (6)	
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:19
	(b) (4), (b) (6)	
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:48
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:11:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '18/Nov/2020 10:40'	System	18 Nov 2020 15:40:31



US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:53

**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)	26 Apr 2021 18:55:14
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 15:40:31

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
	(b) (4), (b) (6)	
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
	(b) (4), (b) (6)	
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:21
	(b) (4), (b) (6)	
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:19
	(b) (4), (b) (6)	
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:48
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51



US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:11:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '24/Nov/2020 20:38'	System	24 Nov 2020 20:38:37

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:53

**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)	26 Apr 2021 18:55:14
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 12:39:10
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 20:38:37

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
	(b) (4), (b) (6)	
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:21
	(b) (4), (b) (6)	
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:19
	(b) (4), (b) (6)	
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:48
	(b) (4), (b) (6)	



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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:11:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '07/Dec/2020 07:39'	System	07 Dec 2020 12:39:19

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:11:53

**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)	26 Apr 2021 18:55:14
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:15:23
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 12:39:19

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	



US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
	(b) (4), (b) (6)	
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
	(b) (4), (b) (6)	
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
	(b) (4), (b) (6)	
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:21
	(b) (4), (b) (6)	
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:19
	(b) (4), (b) (6)	
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:48
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:11:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered '24/Jan/2021 21:15'	System	25 Jan 2021 02:15:32

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:11:53

**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)	26 Apr 2021 18:55:14
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 02:15:32

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered	System	11 Nov 2020 20:53:16
'USA-US067-2020-MRNA-1273-P301000011'		



**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:31:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'Yes (Y)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:32:15
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:53:43
User entered 'No (N)'	System	11 Nov 2020 20:53:16

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:02
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Jon'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:52
	(b) (4), (b) (6)	
User closed query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:50
	(b) (4), (b) (6)	
Query 'Please enter PI's first name (i.e. Nathan)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:34
User entered 'Nathan'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's first name (i.e. Nathan)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:28:35
	(b) (4), (b) (6)	



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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:16:04
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered 'Finley'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:13:57
	(b) (4), (b) (6)	
User closed query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:13:55
	(b) (4), (b) (6)	
Query 'Please enter PI's last name (i.e. Segall)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:37:50
User entered 'Segall'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter PI's last name (i.e. Segall)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:06
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:15:49
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered '175 Country Club Drive'	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:04
	(b) (4), (b) (6)	
User closed query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:02
	(b) (4), (b) (6)	
Query 'Please enter site's street address (i.e. 175 Country Club Drive)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:08
User entered '175 Country Club Drive 100A'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter site's street address (i.e. 175 Country Club Drive)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:39
	(b) (4), (b) (6)	

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:15
	(b) (4), (b) (6)	
User closed query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:13
	(b) (4), (b) (6)	
Query 'Please enter city of site address (i.e. Stockbridge)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:37
User entered 'Stockbridge'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter city of site address (i.e. Stockbridge)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:30:10
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 16:14:21
User closed query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 16:14:19
Query 'Please enter state of Site address (i.e. GA)' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:38:49
User entered 'GA'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter state of Site address (i.e. GA)' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 16:30:48

US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	28 Apr 2021 01:17:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 18:54:29
Signature has been broken.	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User entered '30248' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Apr 2021 14:28:24
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:05:25
DataPoint Un-verified.	System	13 Apr 2021 17:05:25
User entered (b) (4)	System	13 Apr 2021 17:05:25
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:05:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:27
	(b) (4), (b) (6)	
User closed query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:25
	(b) (4), (b) (6)	
Query 'Please enter Zip Code of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:39:03
User entered '30281'	Donna Toepfer (b) (4)	12 Apr 2021 18:37:01
User opened query 'Please enter Zip Code of site address' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:13
	(b) (4), (b) (6)	

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Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:14:34
	(b) (4), (b) (6)	
User closed query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 16:14:31
	(b) (4), (b) (6)	
Query 'Please enter Country of site ' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	12 Apr 2021 18:47:01
User opened query 'Please enter Country of site ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:31:36
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:38:22
User entered 'US'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	13 Apr 2021 17:05:25
User signature succeeded.	Nathan Segall (b) (4)	08 Feb 2021 20:09:42
	(b) (4)	
User entered '5'	System	25 Jan 2021 02:15:32
User entered '4'	System	07 Dec 2020 12:39:19
User entered '3'	System	24 Nov 2020 20:38:37
User entered '2'	System	18 Nov 2020 15:40:31
User entered '1'	System	11 Nov 2020 20:53:51

**US3242051**

**Folder: SAE USA-US067-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:11:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
User entered '13/Apr/2021 13:05'	System	13 Apr 2021 17:05:25



US3242051

Folder: SAE USA-US067-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:11:53

**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)	26 Apr 2021 18:55:14
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	14 Apr 2021 19:43:36
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 17:05:25