

US3242107 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:16:00

All time stamps listed in this document are displayed in GMT

US3242107

Form: Participant Creation

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Participant ID

US3242107

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

US3242107

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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

Visit date (dd MMM yyyy)	15 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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US3242107

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
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) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Date of Informed Consent (<i>dd MMM yyyy</i>)	15 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	01 JAN 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 AUG 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 11:02
Height (xxx.x)	74 in
Weight (xxx.x)	188 lb
BMI (xxx.x)	24.18824 kg/m ²
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) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 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) 10 Feb 2021 19:42:48

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Feb 2021 19:42:48

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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

Visit date (dd MMM yyyy)	15 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) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

What was the date of randomization? (dd MMM yyyy) 15 AUG 2020

What was the participant's randomization number? 186274

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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)	15 AUG 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 11:02
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 AUG 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 12:44
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 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

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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) 15 AUG 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 15 AUG 2020 12:13

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) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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

Collection date (dd MMM yyyy)	15 AUG 2020
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Collection time (00:00-23:59)	11:58 (24 HR)
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Collection date and time (derived)	15 AUG 2020 11:58
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

Collection date (dd MMM yyyy)			15 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:58	15 AUG 2020 11:58
Nasopharyngeal Swab 2	No		

US3242107

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:52

PC Open Date & Time

15 AUG 2020 12:33

PC Close Date & Time

15 AUG 2020 15:03

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 98.2 °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 AUG 2020 21:00
PC Open Date & Time	15 AUG 2020 15:58
PC Close Date & Time	16 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 21:26

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

97.4 °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 AUG 2020 21:04

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

18 AUG 2020 20:17

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

19 AUG 2020 21:40

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 20:28

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:58

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

15 AUG 2020 12:52

PC Open Date & Time

15 AUG 2020 12:33

PC Close Date & Time

15 AUG 2020 15:03

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

15 AUG 2020 21:01

PC Open Date & Time

15 AUG 2020 15:58

PC Close Date & Time

16 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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

16 AUG 2020 21:27

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

17 AUG 2020 21:03

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

18 AUG 2020 20:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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

19 AUG 2020 21:39

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

20 AUG 2020 20:27

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

21 AUG 2020 18:55

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 12:53
PC Open Date & Time	15 AUG 2020 12:33
PC Close Date & Time	15 AUG 2020 15:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 21:01
PC Open Date & Time	15 AUG 2020 15:58
PC Close Date & Time	16 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:28
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:03
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 20:16
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 21:40
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:28
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

56 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 18:55
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3242107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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

Visit date (dd MMM yyyy)	14 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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US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

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)	14 SEP 2020
Time of assessment (00:00-23:59)	9:26 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 9:26
Temperature (xxx.x)	97.3 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

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)	14 SEP 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 10:40
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3242107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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.

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 10:09 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 10:09

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

US3242107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

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

Collection date (dd MMM yyyy)	14 SEP 2020
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Collection time (00:00-23:59)	9:57 (24 HR)
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Collection date and time (derived)	14 SEP 2020 9:57
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US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:50	14 SEP 2020 9:50
Nasopharyngeal Swab 2	No		

US3242107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:49

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 10:54

PC Open Date & Time

14 SEP 2020 10:29

PC Close Date & Time

14 SEP 2020 12:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	15 SEP 2020 10:40
PC Open Date & Time	14 SEP 2020 13:54
PC Close Date & Time	15 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 23:22

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

97.2 °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

17 SEP 2020 18:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:57

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 16:10

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

20 SEP 2020 19:32

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

14 SEP 2020 10:54

PC Open Date & Time

14 SEP 2020 10:29

PC Close Date & Time

14 SEP 2020 12:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

15 SEP 2020 10:37

PC Open Date & Time

14 SEP 2020 13:54

PC Close Date & Time

15 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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

15 SEP 2020 23:21

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

16 SEP 2020 18:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

17 SEP 2020 18:17

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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

18 SEP 2020 19:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

19 SEP 2020 16:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

20 SEP 2020 19:32

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 10:55
PC Open Date & Time	14 SEP 2020 10:29
PC Close Date & Time	14 SEP 2020 12:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 10:38
PC Open Date & Time	14 SEP 2020 13:54
PC Close Date & Time	15 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 ☒

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 23:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

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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94 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:22
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 ☒

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 19:56
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 16:09
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

102 of 2089

EAB) (1725)

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:32
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3242107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

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

Visit date (dd MMM yyyy)	13 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
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US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:09
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

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.

US3242107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

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

Collection date (dd MMM yyyy)	13 OCT 2020
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Collection time (00:00-23:59)	9:28 (24 HR)
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Collection date and time (derived)	13 OCT 2020 9:28
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US3242107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:43:15

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 15:41:04
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

22 OCT 2020 10:40:19

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 13:13:13

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 11:29:25

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 18:55:20
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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	24 NOV 2020 14:21:25
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 00:03:48
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 10:01:38

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 09:52:24
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

21 DEC 2020 10:47:02

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 09:18:33
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

04 JAN 2021 08:27:30

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 JAN 2021 03:03:23
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 14:18:12
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 08:56:34
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

03 FEB 2021 09:11:02

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 09:57:59

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 10:30:02

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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	24 FEB 2021 17:00:52
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 <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 MAR 2021 07:58:46
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

08 MAR 2021 00:40:55

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

15 MAR 2021 22:15:14

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 09:06:38

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 05:25:22

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 14:12:21
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

12 APR 2021 09:16:33

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

20 APR 2021 15:11:36

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

26 APR 2021 09:20:01

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

03 MAY 2021 12:35:02

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 <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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 425

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

Patient Cloud Open Date & Time	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

Patient Cloud Open Date & Time	20 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 ☐
Yes ☐

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

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2022 00:01
Patient Cloud Close Date & Time	21 OCT 2022 23:59

US3242107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:16:00

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 07:59:07

US3242107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:48

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:11:27

Generated On: 09 Jun 2021 16:16:00

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

Visit date (dd MMM yyyy)	23 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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US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:43:21

Generated On: 09 Jun 2021 16:16:00

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) _____

US3242107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:11:27

Generated On: 09 Jun 2021 16:16:00

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.

US3242107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:11:27

Generated On: 09 Jun 2021 16:16:00

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 23 MAR 2021

Collection time (00:00-23:59) 09:28 (24 HR)

Collection date and time (derived) 23 MAR 2021 09:28

US3242107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:11:26

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 13:02:27

Generated On: 09 Jun 2021 16:16:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242107

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 13:02:27

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242107

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242107

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:16:00

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"/>

US3242107

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:16:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3242107

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

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 19 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242107

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:36:58

Generated On: 09 Jun 2021 16:16:00

Date of updated informed consent (dd MMM yyyy) 19 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3242107

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

10:13 (24 HR)

Collection date and time (derived)

19 JAN 2021 10:13

US3242107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	09:58
Collection Date and Time (derived)	19 JAN 2021 09:58

US3242107

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 17:20:07

Generated On: 09 Jun 2021 16:16:00

AEID	USA-US067-2021-MRNA-1273-P30 1000003
Adverse event	CEREBROVASCULAR ACCIDENT
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)	09 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	09 JAN 2020
Hospital Discharge Date (dd MMM yyyy)	12 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 17:20:07

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 17:20:07

Generated On: 09 Jun 2021 16:16:00

ADMITTED TO HOSPITAL WITH
CVA 1/9/2021, TREATED, NO
RESIDUAL BY HISTORY
THOUGH REMAINS IN
HOSPITAL FOR OBSERVATION.
UPDATE, DISCHARGED ON THE
12 JAN 2021. SAR COV-2 TEST,
FLU A, FLU B, RSV DONE ON
1/9/2021-ALL NEGATIVE
CTA HEAD/NECK SHOWED NO
LARGE VESSEL DISEASE AND
MRI SHOWED SUBACUTE LEFT
MCA LACUNAR STROKE. ECHO
SHOWED NO PFO AND NO
ADDITIONAL THERAPY
NEEDED.

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

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 10 Feb 2021 19:42:47

Generated On: 09 Jun 2021 16:16:00

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

Yes ☒

No ☐

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

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	01 JAN 1998	
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"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication DIET SUPPLEMENT

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	01 JAN 2008	
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"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 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"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication LIPITOR

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 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"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication POST CEREBROVASCULAR
ACCIDENT, PROPHYLAXIS FOR
HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 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"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒
No ☐

Indication POST CEREBROVASCULAR
ACCIDENT, PROPHYLAXIS FOR
HEART HEALTH

Dose per administration 75

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 (6)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication ALTEPLASE

Prophylaxis Yes ☐
No ☒

Indication CELEBRAL VASCULAR
ACCIDENT

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify MG/KG

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 (7)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication SODIUM CHLORIDE 9%

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 0.81

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

If dose unit is Other, specify ML/KG/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication IOPAMIDOL 76%

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication ALUMINUM MAGNESIUM
HYDROXIDE SIMETHICONE

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 325

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) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication METHYLPREDNISOLONE
SODIUM SUCC

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify UNITS

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) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication CALCIUM GLUCONATE IN 9%
SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

Name of Medication PERFLUTREN LIPID
MICROSPHERES

Prophylaxis Yes ☐
No ☒

Indication CEREBRAL VASCULAR
ACCIDENT

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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EAB) (1725)

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US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Feb 2021 14:50:47

Generated On: 09 Jun 2021 16:16:00

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Mar 2021 22:02:47

Generated On: 09 Jun 2021 16:16:00

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Mar 2021 22:02:47

Generated On: 09 Jun 2021 16:16:00

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 JAN 2021	ECHO	Adverse Event	
09 JAN 2021	CT/HEAD AND NECK	Adverse Event	
09 JAN 2021	MRI	Adverse Event	

US3242107

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:16:00

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

US3242107

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:16:00

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 ☐

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 21:18:04

Generated On: 09 Jun 2021 16:16:00

SAEID	USA-US067-2021-MRNA-1273-P301000003
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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 21:18:04

Generated On: 09 Jun 2021 16:16:00

SAEID	USA-US067-2021-MRNA-1273-P301000003
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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/JAN/2021 23:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 21:18:04

Generated On: 09 Jun 2021 16:16:00

SAEID	USA-US067-2021-MRNA-1273-P301000003
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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	05/FEB/2021 18:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 21:18:04

Generated On: 09 Jun 2021 16:16:00

SAEID	USA-US067-2021-MRNA-1273-P301000003
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	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/FEB/2021 09:41
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

US3242107 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242107

Form: Participant Creation

Generated On: 09 Jun 2021 16:16:00

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'US3242107'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:14:20

US3242107

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:29

US3242107

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:14:21

US3242107

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:29

US3242107

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'SCRN'	(b) (4), (b) (6) System	15 Aug 2020 16:16:29

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:14:22

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '72'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'YEARS'	(b) (4), (b) (6) System	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '72'	(b) (4), (b) (6) System	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Male (M)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'I'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:16:00

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:40

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Aug 2020'	(b) (4), (b) (6) System	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '2020'	(b) (4), (b) (6) System	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Amendment 2 (2)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:52

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:14:21

US3242107

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:16:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'I'	(b) (4), (b) (6) System	15 Aug 2020 16:16:56

US3242107

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:16:56

US3242107

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:16:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:26:49

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 17:28:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 17:28:24
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 17:27:46
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '01 Jan 1998'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Jan 1998'	(b) (4), (b) (6) System	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '1998'	(b) (4), (b) (6) System	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 17:27:09

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 17:28:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 17:28:24
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 17:27:46
User entered 'Gallstones'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'UN Nov 2019'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'UN Nov 2019'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Nov 2019'	(b) (4), (b) (6) System	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '2019'	(b) (4), (b) (6) System	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Nov 2019'	(b) (4), (b) (6) System	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '2019'	(b) (4), (b) (6) System	15 Aug 2020 17:27:26

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 17:29:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 17:29:24
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 17:28:47
User entered 'Cholecystectomy'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Un Nov 2019'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. '(Site from DM).	(b) (4), (b) (6)	19 Oct 2020 20:05:20
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	17 Sep 2020 17:53:30
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Sep 2020 17:53:24
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. '(Site from DM).	(b) (4), (b) (6)	11 Sep 2020 03:41:08
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'UN Nov 2019' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Sep 2020 17:53:24
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Nov 2019'	(b) (4), (b) (6) System	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '2019'	(b) (4), (b) (6) System	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Nov 2019'	(b) (4), (b) (6)	
	System	17 Sep 2020 17:53:24
User entered empty.	System	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User entered '2019'	System	17 Sep 2020 17:53:24
User entered empty.	System	15 Aug 2020 17:27:55

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 17:29:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 17:29:24
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 17:28:47
User entered 'Vasectomy'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'UN UNK 1970'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'UN UNK 1970'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Jan 1970'	(b) (4), (b) (6) System	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '1970'	(b) (4), (b) (6) System	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Jan 1970'	(b) (4), (b) (6) System	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '1970'	(b) (4), (b) (6) System	15 Aug 2020 17:28:12

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 16:02:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 16:02:01
	(b) (4)	
Data point term sent to Coder	System	13 Jan 2021 16:01:10
User entered 'hyperlipidemia'	Donna Toepfer (b) (4)	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'un UNK 2010'	Donna Toepfer (b) (4)	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '0'	Donna Toepfer (b) (4)	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Donna Toepfer (b) (4)	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '0'	Donna Toepfer (b) (4)	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'Jan 2010'	(b) (4), (b) (6) System	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '2010'	(b) (4), (b) (6) System	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 16:00:21

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:29:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	15 Aug 2020 17:29:02
User entered '11:02' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Aug 2020 17:29:02
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Aug 2020 17:28:50
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '15 Aug 2020 11:02'	(b) (4), (b) (6)	
	System	15 Aug 2020 17:29:02
User entered empty.	System	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '74' in	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50
DataPoint set to visible.	System	15 Aug 2020 16:16:56

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '188' lb	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50
DataPoint set to visible.	System	15 Aug 2020 16:16:56

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
Amendment Manager: User entered '24.18824'	(b) (4), (b) (6)	
User entered '24.2'	System	16 Sep 2020 23:58:34
DataPoint set to visible.	System	15 Aug 2020 17:28:50
	System	15 Aug 2020 16:16:56

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'kg/m2'	(b) (4), (b) (6)	
	System	15 Aug 2020 17:28:50
DataPoint set to visible.	System	15 Aug 2020 16:16:56

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
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)	24 Sep 2020 11:19:46
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 23:30:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 23:30:34
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 11:34:50
User entered '97.2' F	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 23:30:34
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
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)	24 Sep 2020 11:19:48
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 23:30:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 23:30:34
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 11:34:58
User entered '72'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
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)	24 Sep 2020 11:19:49
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 23:30:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 23:30:34
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 11:35:04
User entered '12'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
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)	24 Sep 2020 11:19:53
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 23:30:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 23:30:34
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 11:35:11
User entered '118'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
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)	24 Sep 2020 11:19:55
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 23:30:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	15 Sep 2020 23:30:34
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 11:35:16
User entered '72'	Donna Toepfer (b) (4)	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 17:28:50

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:45:43

US3242107

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:45:43

US3242107

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:10

US3242107

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.'	(b) (4), (b) (6)	23 Sep 2020 16:55:53
canceled (Site from System).		
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 14:01:56
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:10

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'I'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '0'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:16:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:29:35

US3242107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:07

US3242107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:07

US3242107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[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 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:07

US3242107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'VISIT1'	System	15 Aug 2020 16:17:07

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:59:23

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:48:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:48:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 15:59:23
User entered '186274' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:59:23

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 15:59:23

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:17

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:17

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:17

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:17

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:17

US3242107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Erynn McKinley (b) (4)	23 Sep 2020 17:27:52
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:28:56

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:16:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 17:51:34
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 21:13:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 21:13:53
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:21:04
User entered '74' in	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:16:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query '	(b) (4), (b) (6)	02 Sep 2020 17:51:39
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 21:14:05
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 21:13:53
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:21:08
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '198' lb	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:16:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 17:51:34
Query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	31 Aug 2020 21:13:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Donna Toepfer (b) (4)	31 Aug 2020 21:13:53
User opened query ' Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:21:04
User entered '74' in	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:16:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query '	(b) (4), (b) (6)	02 Sep 2020 17:51:39
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 21:14:05
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 21:13:53
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:21:08
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '198' lb	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '11:02'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '15 Aug 2020 11:02'	(b) (4), (b) (6)	15 Aug 2020 17:33:39
	System	

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '97.2' F	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '72'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'bpm'	System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '12'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '118'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '72'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:16:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query '	(b) (4), (b) (6)	02 Sep 2020 17:51:34
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 21:13:58
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 21:13:53
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:21:04
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '74' in	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:16:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User closed query '	(b) (4), (b) (6)	02 Sep 2020 17:51:39
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
Query '	Donna Toepfer (b) (4)	31 Aug 2020 21:14:05
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' answered with		
'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for	Donna Toepfer (b) (4)	31 Aug 2020 21:13:53
change Data Entry Error		
User opened query '	(b) (4), (b) (6)	28 Aug 2020 18:21:08
Per CDM: Response noted, however per CCG's pages		
15-16, Height and Weight should be entered as "ND".		
Please review and update else clarify' (Site from		
DM).		
User entered '198' lb	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
	(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)	18 Aug 2020 15:31:12
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	15 Aug 2020 17:33:47
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		15 Aug 2020 17:33:39
User entered '12:44'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '15 Aug 2020 12:44'	(b) (4), (b) (6)	15 Aug 2020 17:33:39
	System	

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '97.0' F	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '68'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'bpm'	System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '12'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '128'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '80'	Donna Toepfer (b) (4)	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 17:33:39

US3242107

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:25

US3242107

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:18:25

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

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 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	15 Aug 2020 16:17:53
	System	

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '12:13'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '15 Aug 2020 12:13'	(b) (4), (b) (6)	15 Aug 2020 16:17:53
	System	

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Sep 2020 14:19:22
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'ONCE'	System	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:05

US3242107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:05

US3242107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '11:58'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:05

US3242107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '15 Aug 2020 11:58'	(b) (4), (b) (6)	15 Aug 2020 16:18:05
	System	

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:16:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '15 Aug 2020'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered '11:58'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '15 Aug 2020 11:58'	(b) (4), (b) (6)	15 Aug 2020 16:18:16
	System	

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered empty.	Donna Toepfer (b) (4)	15 Aug 2020 16:18:16

US3242107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 16:18:16
	System	

US3242107

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:31:00
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 16:18:20

US3242107

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	System	15 Aug 2020 16:18:20

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:51:39', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b77017e7-751d-4128-abb1-6420ce2a2c2d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Aug 2020 16:52:06
	System	15 Aug 2020 16:52:06

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:51:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b77017e7-751d-4128-abb1-6420ce2a2c2d' User entered '97.0'	(b) (4), (b) (6) System	15 Aug 2020 16:52:06
	System	15 Aug 2020 16:52:06

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:51:55', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b77017e7-751d-4128-abb1-6420ce2a2c2d' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 16:52:06
	System	15 Aug 2020 16:52:06

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:52:05', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b77017e7-751d-4128-abb1-6420ce2a2c2d' User entered '15 Aug 2020 12:52'	(b) (4), (b) (6) System	15 Aug 2020 16:52:06
	System	15 Aug 2020 16:52:06

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 12:33'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 15:03'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T20:59:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4dcc668f-6ab3-41aa-b246-ed2a3690ff90' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Aug 2020 01:00:37
	System	16 Aug 2020 01:00:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:00:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4dcc668f-6ab3-41aa-b246-ed2a3690ff90' User entered '98.2'	(b) (4), (b) (6) System	16 Aug 2020 01:00:37
	System	16 Aug 2020 01:00:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:00:27', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4dcc668f-6ab3-41aa-b246-ed2a3690ff90' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 01:00:37
	System	16 Aug 2020 01:00:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:00:35', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4dcc668f-6ab3-41aa-b246-ed2a3690ff90' User entered '15 Aug 2020 21:00'	(b) (4), (b) (6) System	16 Aug 2020 01:00:37
	System	16 Aug 2020 01:00:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 15:58'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 2'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:25:45', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '677794cb-3d84-44a7-98e3-b6b5f30fba5c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Aug 2020 01:26:17
	System	17 Aug 2020 01:26:17

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:05', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '677794cb-3d84-44a7-98e3-b6b5f30fba5c' User entered '97.5'	(b) (4), (b) (6) System	17 Aug 2020 01:26:17
	System	17 Aug 2020 01:26:17

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:08', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '677794cb-3d84-44a7-98e3-b6b5f30fba5c' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 01:26:17
	System	17 Aug 2020 01:26:17

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:16', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '677794cb-3d84-44a7-98e3-b6b5f30fba5c' User entered '16 Aug 2020 21:26'	(b) (4), (b) (6) System	17 Aug 2020 01:26:17
	System	17 Aug 2020 01:26:17

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 3'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:04:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0d83a3af-bdee-41b2-8ec4-0913d2840c11' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:42
	System	18 Aug 2020 01:04:42

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:04:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0d83a3af-bdee-41b2-8ec4-0913d2840c11' User entered '97.4'	(b) (4), (b) (6) System	18 Aug 2020 01:04:42
	System	18 Aug 2020 01:04:42

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:04:37', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0d83a3af-bdee-41b2-8ec4-0913d2840c11' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:42
	System	18 Aug 2020 01:04:42

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:04:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0d83a3af-bdee-41b2-8ec4-0913d2840c11' User entered '17 Aug 2020 21:04'	(b) (4), (b) (6) System	18 Aug 2020 01:04:42
	System	18 Aug 2020 01:04:42

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 4'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:17:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6331ef28-d2d8-496f-a553-0c10a7a209db' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Aug 2020 00:17:37
	System	19 Aug 2020 00:17:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:17:26', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6331ef28-d2d8-496f-a553-0c10a7a209db' User entered '97.7'	(b) (4), (b) (6) System	19 Aug 2020 00:17:37
	System	19 Aug 2020 00:17:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:17:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6331ef28-d2d8-496f-a553-0c10a7a209db' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 00:17:37
	System	19 Aug 2020 00:17:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:17:33', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6331ef28-d2d8-496f-a553-0c10a7a209db' User entered '18 Aug 2020 20:17'	(b) (4), (b) (6) System	19 Aug 2020 00:17:37
	System	19 Aug 2020 00:17:37

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 5'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:31', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7576cf2d-f0b2-4233-b122-af8d58927390' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:55
	System	20 Aug 2020 01:40:55

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7576cf2d-f0b2-4233-b122-af8d58927390' User entered '97.4'	(b) (4), (b) (6) System	20 Aug 2020 01:40:55
	System	20 Aug 2020 01:40:55

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:45', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7576cf2d-f0b2-4233-b122-af8d58927390'	(b) (4), (b) (6) System	20 Aug 2020 01:40:55
User entered 'No (N)'	System	20 Aug 2020 01:40:55

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7576cf2d-f0b2-4233-b122-af8d58927390' User entered '19 Aug 2020 21:40'	(b) (4), (b) (6) System	20 Aug 2020 01:40:55
	System	20 Aug 2020 01:40:55

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 6'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:28:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cbbdc19c-ffb7-46bf-bf4d-954888b697c3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:32
	System	21 Aug 2020 00:28:32

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:28:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cbbdc19c-ffb7-46bf-bf4d-954888b697c3' User entered '98.2'	(b) (4), (b) (6) System	21 Aug 2020 00:28:32
	System	21 Aug 2020 00:28:32

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:28:27', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cbbdc19c-ffb7-46bf-bf4d-954888b697c3'	(b) (4), (b) (6) System	21 Aug 2020 00:28:32
User entered 'No (N)'	System	21 Aug 2020 00:28:32

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:28:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cbbdc19c-ffb7-46bf-bf4d-954888b697c3' User entered '20 Aug 2020 20:28'	(b) (4), (b) (6) System	21 Aug 2020 00:28:32
	System	21 Aug 2020 00:28:32

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 7'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c004ea21-4a3b-4a86-ab73-a76c34907493' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 22:58:11
	System	21 Aug 2020 22:58:11

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:57:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c004ea21-4a3b-4a86-ab73-a76c34907493' User entered '97.7'	(b) (4), (b) (6) System	21 Aug 2020 22:58:11
	System	21 Aug 2020 22:58:11

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:58:03', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c004ea21-4a3b-4a86-ab73-a76c34907493'	(b) (4), (b) (6)	21 Aug 2020 22:58:11
User entered 'No (N)'	System	21 Aug 2020 22:58:11

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:58:08', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c004ea21-4a3b-4a86-ab73-a76c34907493' User entered '21 Aug 2020 18:58'	(b) (4), (b) (6) System	21 Aug 2020 22:58:11
	System	21 Aug 2020 22:58:11

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:52:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '256a1908-7c10-4fff-a1cf-9e8a6b195bc7'	(b) (4), (b) (6) System	15 Aug 2020 16:52:57
User entered 'None (1)'	System	15 Aug 2020 16:52:57

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:52:31', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '256a1908-7c10-4fff-a1cf-9e8a6b195bc7'	(b) (4), (b) (6)	
	System	15 Aug 2020 16:52:57
User entered 'No (N)'	System	15 Aug 2020 16:52:57

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:52:35', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '256a1908-7c10-4fff-a1cf-9e8a6b195bc7' User entered 'No (N)'	(b) (4), (b) (6) System	15 Aug 2020 16:52:57
	System	15 Aug 2020 16:52:57

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:52:46', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '256a1908-7c10-4fff-a1cf-9e8a6b195bc7'	(b) (4), (b) (6) System	15 Aug 2020 16:52:57
User entered 'None (1)'	System	15 Aug 2020 16:52:57

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:52:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '256a1908-7c10-4fff-a1cf-9e8a6b195bc7' User entered '15 Aug 2020 12:52'	(b) (4), (b) (6) System	15 Aug 2020 16:52:57
	System	15 Aug 2020 16:52:57

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 12:33'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 15:03'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:00:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6e4d96ac-9f05-4101-9ba5-c3b9bec011af' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:17
	System	16 Aug 2020 01:01:17

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:00:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6e4d96ac-9f05-4101-9ba5-c3b9bec011af' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:17
	System	16 Aug 2020 01:01:17

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:00:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6e4d96ac-9f05-4101-9ba5-c3b9bec011af' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:17
	System	16 Aug 2020 01:01:17

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:04', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6e4d96ac-9f05-4101-9ba5-c3b9bec011af' User entered 'None (1)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:17
	System	16 Aug 2020 01:01:17

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6e4d96ac-9f05-4101-9ba5-c3b9bec011af' User entered '15 Aug 2020 21:01'	(b) (4), (b) (6) System	16 Aug 2020 01:01:17
	System	16 Aug 2020 01:01:17

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 15:58'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 2'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7e8c69cf-9033-4015-943f-d6313ed36c14' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 01:27:12
	System	17 Aug 2020 01:27:12

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:28', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7e8c69cf-9033-4015-943f-d6313ed36c14' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 01:27:12
	System	17 Aug 2020 01:27:12

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:44', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7e8c69cf-9033-4015-943f-d6313ed36c14' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 01:27:12
	System	17 Aug 2020 01:27:12

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:26:53', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7e8c69cf-9033-4015-943f-d6313ed36c14' User entered 'None (1)'	(b) (4), (b) (6) System	17 Aug 2020 01:27:12
	System	17 Aug 2020 01:27:12

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:27:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7e8c69cf-9033-4015-943f-d6313ed36c14' User entered '16 Aug 2020 21:27'	(b) (4), (b) (6) System	17 Aug 2020 01:27:12
	System	17 Aug 2020 01:27:12

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 3'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60cf26ed-635f-4e90-9e06-9d3c0e61d1c0' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 01:03:32
	System	18 Aug 2020 01:03:32

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:06', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60cf26ed-635f-4e90-9e06-9d3c0e61d1c0' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:03:32
	System	18 Aug 2020 01:03:32

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60cf26ed-635f-4e90-9e06-9d3c0e61d1c0' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:03:32
	System	18 Aug 2020 01:03:32

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60cf26ed-635f-4e90-9e06-9d3c0e61d1c0' User entered 'None (1)'	(b) (4), (b) (6) System	18 Aug 2020 01:03:32
	System	18 Aug 2020 01:03:32

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:28', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60cf26ed-635f-4e90-9e06-9d3c0e61d1c0' User entered '17 Aug 2020 21:03'	(b) (4), (b) (6) System	18 Aug 2020 01:03:32
	System	18 Aug 2020 01:03:32

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 4'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:12:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'eea5cad7-6d45-4de8-af9d-c1d8007d73da' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 00:13:14
	System	19 Aug 2020 00:13:14

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:13:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'eea5cad7-6d45-4de8-af9d-c1d8007d73da' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 00:13:14
	System	19 Aug 2020 00:13:14

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:13:04', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'eea5cad7-6d45-4de8-af9d-c1d8007d73da' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 00:13:14
	System	19 Aug 2020 00:13:14

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:13:07', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'eea5cad7-6d45-4de8-af9d-c1d8007d73da' User entered 'None (1)'	(b) (4), (b) (6) System	19 Aug 2020 00:13:14
	System	19 Aug 2020 00:13:14

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:13:11', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'eea5cad7-6d45-4de8-af9d-c1d8007d73da' User entered '18 Aug 2020 20:13'	(b) (4), (b) (6) System	19 Aug 2020 00:13:14
	System	19 Aug 2020 00:13:14

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 5'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:39:39', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c02a593e-783e-4f93-93ed-6a6f5d8d2473' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:02
	System	20 Aug 2020 01:40:02

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:39:43', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c02a593e-783e-4f93-93ed-6a6f5d8d2473' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:02
	System	20 Aug 2020 01:40:02

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:39:45', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c02a593e-783e-4f93-93ed-6a6f5d8d2473' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:02
	System	20 Aug 2020 01:40:02

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:39:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c02a593e-783e-4f93-93ed-6a6f5d8d2473' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:02
	System	20 Aug 2020 01:40:02

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:39:56', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c02a593e-783e-4f93-93ed-6a6f5d8d2473' User entered '19 Aug 2020 21:39'	(b) (4), (b) (6) System	20 Aug 2020 01:40:02
	System	20 Aug 2020 01:40:02

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 6'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '79e53b9e-48ec-48e1-b057-28e6b6be5b67' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 00:27:27
	System	21 Aug 2020 00:27:27

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '79e53b9e-48ec-48e1-b057-28e6b6be5b67' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 00:27:27
	System	21 Aug 2020 00:27:27

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:18', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '79e53b9e-48ec-48e1-b057-28e6b6be5b67' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 00:27:27
	System	21 Aug 2020 00:27:27

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '79e53b9e-48ec-48e1-b057-28e6b6be5b67' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 00:27:27
	System	21 Aug 2020 00:27:27

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '79e53b9e-48ec-48e1-b057-28e6b6be5b67' User entered '20 Aug 2020 20:27'	(b) (4), (b) (6) System	21 Aug 2020 00:27:27
	System	21 Aug 2020 00:27:27

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 7'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:54:53', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2a5660a0-2f37-4766-b802-08cb78d34fd8' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:18
	System	21 Aug 2020 22:55:18

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:54:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2a5660a0-2f37-4766-b802-08cb78d34fd8' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:18
	System	21 Aug 2020 22:55:18

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:06', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2a5660a0-2f37-4766-b802-08cb78d34fd8' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:18
	System	21 Aug 2020 22:55:18

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2a5660a0-2f37-4766-b802-08cb78d34fd8' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:18
	System	21 Aug 2020 22:55:18

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2a5660a0-2f37-4766-b802-08cb78d34fd8' User entered '21 Aug 2020 18:55'	(b) (4), (b) (6) System	21 Aug 2020 22:55:18
	System	21 Aug 2020 22:55:18

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:28', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:31', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:33', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered 'None (0)'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:36', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
User entered 'No (N)'	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T12:53:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0fc87329-d463-4591-83ff-1c130c7db0df' User entered '15 Aug 2020 12:53'	(b) (4), (b) (6) System	15 Aug 2020 16:53:45
	System	15 Aug 2020 16:53:45

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 12:33'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 15:03'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:18', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:26', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:29', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:34', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'None (0)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:38', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered 'No (N)'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-15T21:01:43', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '556d40e6-274d-4a6a-915b-b8a19f081364' User entered '15 Aug 2020 21:01'	(b) (4), (b) (6) System	16 Aug 2020 01:01:46
	System	16 Aug 2020 01:01:46

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Aug 2020 15:58'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 2'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:27:16', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:27:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:27:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:27:57', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:27:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:28:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'None (0)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:28:06', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered 'No (N)'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-16T21:28:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7005b31a-db28-4572-b3f3-8682567c24c7' User entered '16 Aug 2020 21:28'	(b) (4), (b) (6) System	17 Aug 2020 01:28:15
	System	17 Aug 2020 01:28:15

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 3'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:35', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:38', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:43', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:46', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'None (0)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered 'No (N)'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-17T21:03:56', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd3f175c4-1a9d-447e-9a78-dbb66db7332b' User entered '17 Aug 2020 21:03'	(b) (4), (b) (6) System	18 Aug 2020 01:04:01
	System	18 Aug 2020 01:04:01

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 4'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:36', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:39', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:43', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:46', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'None (0)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:54', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered 'No (N)'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-18T20:16:57', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1e24d8d6-dce0-4243-a146-8bf9308d656a' User entered '18 Aug 2020 20:16'	(b) (4), (b) (6) System	19 Aug 2020 00:16:59
	System	19 Aug 2020 00:16:59

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 5'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:01', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:03', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:06', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:08', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:11', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:13', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-19T21:40:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4132e029-b97e-4ccd-9134-89ecb68335a0' User entered '19 Aug 2020 21:40'	(b) (4), (b) (6) System	20 Aug 2020 01:40:27
	System	20 Aug 2020 01:40:27

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 6'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:35', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:45', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:55', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:27:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-20T20:28:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '91d65860-edc4-4675-9833-c8372002cc21' User entered '20 Aug 2020 20:28'	(b) (4), (b) (6) System	21 Aug 2020 00:28:03
	System	21 Aug 2020 00:28:03

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 7'	System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:35', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:38', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-08-21T18:55:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0f83490d-e7fc-4c98-8961-da50bee30d2a' User entered '21 Aug 2020 18:55'	(b) (4), (b) (6) System	21 Aug 2020 22:55:43
	System	21 Aug 2020 22:55:43

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:03:23

US3242107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:03:23

US3242107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Aug 2020 14:03:23

US3242107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:03:23

US3242107

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:03:15

US3242107

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 14:03:15
	System	

US3242107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Yes (Y)'	Grace Newville (b) (4)	31 Aug 2020 20:55:31
	(b) (4)	

US3242107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered '31 Aug 2020'	Grace Newville (b) (4)	31 Aug 2020 20:55:31
	(b) (4)	

US3242107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	31 Aug 2020 20:55:31
	(b) (4)	

US3242107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Grace Newville (b) (4)	31 Aug 2020 20:55:31
	(b) (4)	

US3242107

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Yes (Y)'	Grace Newville (b) (4)	31 Aug 2020 20:55:35
	(b) (4)	

US3242107

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	System	31 Aug 2020 20:55:35

US3242107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:48:41

US3242107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 20:48:41

US3242107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 20:48:41

US3242107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:30:19
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 20:48:41

US3242107

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 20:48:09

US3242107

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	(b) (4), (b) (6)	08 Sep 2020 20:48:09
	System	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 14:01:56
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '14 Sep 2020'	Erynn McKinley (b) (4)	14 Sep 2020 14:01:56
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	14 Sep 2020 14:01:56
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'VISIT2'	System	14 Sep 2020 14:01:56

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '14 Sep 2020'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '9:26'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '14 Sep 2020 9:26'	(b) (4), (b) (6)	
	System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '97.3' F	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered empty.	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '68'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'bpm'	System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '18'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'breaths/min'	(b) (4), (b) (6)	14 Sep 2020 15:26:06
	System	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '130'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '82'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:16:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '14 Sep 2020'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '10:40'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '14 Sep 2020 10:40'	(b) (4), (b) (6)	
	System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '97.4' F	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered empty.	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '64'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'bpm'	System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '16'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'breaths/min'	System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '130'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '82'	Erynn McKinley (b) (4)	14 Sep 2020 15:26:06
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'mmHg'	(b) (4), (b) (6) System	14 Sep 2020 15:26:06

US3242107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'No (N)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:03
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	14 Sep 2020 14:02:03
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 14:12:12
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	14 Sep 2020 14:12:12
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

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 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	14 Sep 2020 14:12:12
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	14 Sep 2020 14:12:12
	System	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '14 Sep 2020'	Erynn McKinley (b) (4)	14 Sep 2020 14:12:12
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '10:09'	Erynn McKinley (b) (4)	14 Sep 2020 14:12:12
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '14 Sep 2020 10:09'	(b) (4), (b) (6)	14 Sep 2020 14:12:12
	System	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	14 Sep 2020 14:19:22
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	14 Sep 2020 14:19:22
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	14 Sep 2020 14:12:12
User entered 'Right Arm (RIGHT ARM)'	Erynn McKinley (b) (4)	14 Sep 2020 14:12:12
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'ONCE'	System	14 Sep 2020 14:12:12

US3242107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:16:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:24
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:58:02
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCF entered' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 12:38:57
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 06:25:53
User entered '14 Sep 2020'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:24
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '9:57'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:24
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '14 Sep 2020 9:57'	(b) (4), (b) (6)	14 Sep 2020 14:02:24
	System	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:16:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:44:42
User closed query 'Per GCL Lab Recon: Covid Assessment page has not been fille out. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:13:12
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'should be Vs 2 Day 29' (Site from DM).	Donna Toepfer (b) (4)	03 Nov 2020 15:09:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 04:58:13
Query 'Per GCL Lab Recon: Covid Assessment page has not been fille out. Please reconcile. ' answered with 'no covid assessments for this subject ' (Site from DM).	Donna Toepfer (b) (4)	26 Oct 2020 14:28:50
User opened query 'Per GCL Lab Recon: Covid Assessment page has not been fille out. Please reconcile. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	25 Oct 2020 19:59:56

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:16:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 19:59:56
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCf entered' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	Donna Toepfer (b) (4)	22 Oct 2020 19:11:02
User entered '14 Sep 2020'	Erynn McKinley (b) (4)	22 Oct 2020 17:34:24
	(b) (4)	14 Sep 2020 14:02:45

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:45
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:45
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '9:50'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:45
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '14 Sep 2020 9:50'	System	14 Sep 2020 14:02:45

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:45
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'No (N)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:45
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	14 Sep 2020 14:02:45
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:02:45
	System	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Sep 2020 14:02:51
	(b) (4)	

US3242107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	System	14 Sep 2020 14:02:51

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:53:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9fc50f31-1b92-4310-b3e6-ab065435f093' User entered 'Yes (Y)'	(b) (4), (b) (6) System	14 Sep 2020 14:54:17
	System	14 Sep 2020 14:54:17

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:53:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9fc50f31-1b92-4310-b3e6-ab065435f093' User entered '97.4'	(b) (4), (b) (6) System	14 Sep 2020 14:54:17
	System	14 Sep 2020 14:54:17

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:04', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9fc50f31-1b92-4310-b3e6-ab065435f093'	(b) (4), (b) (6)	
	System	14 Sep 2020 14:54:17
User entered 'No (N)'	System	14 Sep 2020 14:54:17

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9fc50f31-1b92-4310-b3e6-ab065435f093' User entered '14 Sep 2020 10:54'	(b) (4), (b) (6) System	14 Sep 2020 14:54:17
	System	14 Sep 2020 14:54:17

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 10:29'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 12:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4f2f91e6-e6c9-40eb-be26-310861baf348'	(b) (4), (b) (6) System	15 Sep 2020 14:40:48
User entered 'Yes (Y)'	System	15 Sep 2020 14:40:48

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:40:33', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4f2f91e6-e6c9-40eb-be26-310861baf348' User entered '97.3'	(b) (4), (b) (6) System	15 Sep 2020 14:40:48
	System	15 Sep 2020 14:40:48

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:40:39', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4f2f91e6-e6c9-40eb-be26-310861baf348'	(b) (4), (b) (6) System	15 Sep 2020 14:40:48
User entered 'No (N)'	System	15 Sep 2020 14:40:48

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:40:43', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4f2f91e6-e6c9-40eb-be26-310861baf348'	(b) (4), (b) (6) System	15 Sep 2020 14:40:48
User entered '15 Sep 2020 10:40'	System	15 Sep 2020 14:40:48

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 13:54'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 2'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:55', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '78f41b1d-9043-4eb9-89d1-a51ab4a904da' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 03:22:20
	System	16 Sep 2020 03:22:20

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:22:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '78f41b1d-9043-4eb9-89d1-a51ab4a904da' User entered '97.0'	(b) (4), (b) (6) System	16 Sep 2020 03:22:20
	System	16 Sep 2020 03:22:20

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:22:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '78f41b1d-9043-4eb9-89d1-a51ab4a904da' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 03:22:20
	System	16 Sep 2020 03:22:20

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:22:18', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '78f41b1d-9043-4eb9-89d1-a51ab4a904da' User entered '15 Sep 2020 23:22'	(b) (4), (b) (6) System	16 Sep 2020 03:22:20
	System	16 Sep 2020 03:22:20

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 3'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:37', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a65091d8-4003-4ac8-bd26-2215f3c78f5a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 22:23:00
	System	16 Sep 2020 22:23:00

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:51', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a65091d8-4003-4ac8-bd26-2215f3c78f5a' User entered '97.6'	(b) (4), (b) (6) System	16 Sep 2020 22:23:00
	System	16 Sep 2020 22:23:00

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:55', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a65091d8-4003-4ac8-bd26-2215f3c78f5a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:23:00
	System	16 Sep 2020 22:23:00

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a65091d8-4003-4ac8-bd26-2215f3c78f5a' User entered '16 Sep 2020 18:22'	(b) (4), (b) (6) System	16 Sep 2020 22:23:00
	System	16 Sep 2020 22:23:00

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 4'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'afcddec2f-c438-4b5f-b27d-055c3d8a0ece' User entered 'Yes (Y)'	(b) (4), (b) (6) System	17 Sep 2020 22:18:31
	System	17 Sep 2020 22:18:31

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:18:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'afcddec2f-c438-4b5f-b27d-055c3d8a0ece' User entered '97.2'	(b) (4), (b) (6) System	17 Sep 2020 22:18:31
	System	17 Sep 2020 22:18:31

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:18:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'afcddec2f-c438-4b5f-b27d-055c3d8a0ece'	(b) (4), (b) (6)	17 Sep 2020 22:18:31
User entered 'No (N)'	System	17 Sep 2020 22:18:31

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:18:26', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'afcddec2f-c438-4b5f-b27d-055c3d8a0ece' User entered '17 Sep 2020 18:18'	(b) (4), (b) (6) System	17 Sep 2020 22:18:31
	System	17 Sep 2020 22:18:31

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 5'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:44', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a407db0c-2e6d-4af5-89ba-cbb81959cd7d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	18 Sep 2020 23:57:08
	System	18 Sep 2020 23:57:08

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a407db0c-2e6d-4af5-89ba-cbb81959cd7d' User entered '97.5'	(b) (4), (b) (6) System	18 Sep 2020 23:57:08
	System	18 Sep 2020 23:57:08

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:57:03', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a407db0c-2e6d-4af5-89ba-cbb81959cd7d' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 23:57:08
	System	18 Sep 2020 23:57:08

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:57:05', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a407db0c-2e6d-4af5-89ba-cbb81959cd7d' User entered '18 Sep 2020 19:57'	(b) (4), (b) (6) System	18 Sep 2020 23:57:08
	System	18 Sep 2020 23:57:08

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 6'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cf5f943a-7957-4341-8abf-2af182c777f1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	19 Sep 2020 20:10:26
	System	19 Sep 2020 20:10:26

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:10:17', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cf5f943a-7957-4341-8abf-2af182c777f1' User entered '97.8'	(b) (4), (b) (6) System	19 Sep 2020 20:10:26
	System	19 Sep 2020 20:10:26

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:10:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cf5f943a-7957-4341-8abf-2af182c777f1' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 20:10:26
	System	19 Sep 2020 20:10:26

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:10:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'cf5f943a-7957-4341-8abf-2af182c777f1' User entered '19 Sep 2020 16:10'	(b) (4), (b) (6) System	19 Sep 2020 20:10:26
	System	19 Sep 2020 20:10:26

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 7'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:42', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '195efa74-e159-44ef-b17a-c25248423fb1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Sep 2020 23:33:01
	System	20 Sep 2020 23:33:01

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:53', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '195efa74-e159-44ef-b17a-c25248423fb1' User entered '97.3'	(b) (4), (b) (6) System	20 Sep 2020 23:33:01
	System	20 Sep 2020 23:33:01

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:56', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '195efa74-e159-44ef-b17a-c25248423fb1' User entered 'No (N)'	(b) (4), (b) (6) System	20 Sep 2020 23:33:01
	System	20 Sep 2020 23:33:01

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '195efa74-e159-44ef-b17a-c25248423fb1' User entered '20 Sep 2020 19:32'	(b) (4), (b) (6) System	20 Sep 2020 23:33:01
	System	20 Sep 2020 23:33:01

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'abe79d99-8fbc-4cbd-a45a-e39c570f90af' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 14:54:59
	System	14 Sep 2020 14:54:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'abe79d99-8fbc-4cbd-a45a-e39c570f90af' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 14:54:59
	System	14 Sep 2020 14:54:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:39', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'abe79d99-8fbc-4cbd-a45a-e39c570f90af' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 14:54:59
	System	14 Sep 2020 14:54:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:45', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'abe79d99-8fbc-4cbd-a45a-e39c570f90af' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 14:54:59
	System	14 Sep 2020 14:54:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:54:55', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'abe79d99-8fbc-4cbd-a45a-e39c570f90af' User entered '14 Sep 2020 10:54'	(b) (4), (b) (6) System	14 Sep 2020 14:54:59
	System	14 Sep 2020 14:54:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 10:29'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 12:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:37:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3b35c560-f8d6-45dc-b3b8-7640d2389ab8' User entered 'None (1)'	(b) (4), (b) (6) System	15 Sep 2020 14:37:59
	System	15 Sep 2020 14:37:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:37:34', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3b35c560-f8d6-45dc-b3b8-7640d2389ab8' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:37:59
	System	15 Sep 2020 14:37:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:37:50', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3b35c560-f8d6-45dc-b3b8-7640d2389ab8' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:37:59
	System	15 Sep 2020 14:37:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:37:53', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3b35c560-f8d6-45dc-b3b8-7640d2389ab8' User entered 'None (1)'	(b) (4), (b) (6) System	15 Sep 2020 14:37:59
	System	15 Sep 2020 14:37:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:37:57', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3b35c560-f8d6-45dc-b3b8-7640d2389ab8' User entered '15 Sep 2020 10:37'	(b) (4), (b) (6) System	15 Sep 2020 14:37:59
	System	15 Sep 2020 14:37:59

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 13:54'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 2'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:07', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fcea1672-6f1c-4c56-a888-0fbd2df2594a' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:25
	System	16 Sep 2020 03:21:25

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fcea1672-6f1c-4c56-a888-0fbd2df2594a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:25
	System	16 Sep 2020 03:21:25

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:13', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fcea1672-6f1c-4c56-a888-0fbd2df2594a' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:25
	System	16 Sep 2020 03:21:25

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fcea1672-6f1c-4c56-a888-0fbd2df2594a' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:25
	System	16 Sep 2020 03:21:25

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fcea1672-6f1c-4c56-a888-0fbd2df2594a' User entered '15 Sep 2020 23:21'	(b) (4), (b) (6) System	16 Sep 2020 03:21:25
	System	16 Sep 2020 03:21:25

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 3'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:21:49', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7bd22616-d849-413a-9a49-0cd46ed5dda0'	(b) (4), (b) (6)	16 Sep 2020 22:22:05
User entered 'None (1)'	System	16 Sep 2020 22:22:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:21:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7bd22616-d849-413a-9a49-0cd46ed5dda0' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:05
	System	16 Sep 2020 22:22:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:21:55', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7bd22616-d849-413a-9a49-0cd46ed5dda0' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:05
	System	16 Sep 2020 22:22:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:21:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7bd22616-d849-413a-9a49-0cd46ed5dda0' User entered 'None (1)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:05
	System	16 Sep 2020 22:22:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7bd22616-d849-413a-9a49-0cd46ed5dda0' User entered '16 Sep 2020 18:22'	(b) (4), (b) (6) System	16 Sep 2020 22:22:05
	System	16 Sep 2020 22:22:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 4'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:16:50', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1cd1ed44-d55d-4943-829f-04c7d6b71582'	(b) (4), (b) (6) System	17 Sep 2020 22:17:05
User entered 'None (1)'	System	17 Sep 2020 22:17:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:16:53', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1cd1ed44-d55d-4943-829f-04c7d6b71582' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:05
	System	17 Sep 2020 22:17:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:16:56', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1cd1ed44-d55d-4943-829f-04c7d6b71582' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:05
	System	17 Sep 2020 22:17:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:16:58', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1cd1ed44-d55d-4943-829f-04c7d6b71582' User entered 'None (1)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:05
	System	17 Sep 2020 22:17:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1cd1ed44-d55d-4943-829f-04c7d6b71582' User entered '17 Sep 2020 18:17'	(b) (4), (b) (6) System	17 Sep 2020 22:17:05
	System	17 Sep 2020 22:17:05

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 5'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:55:36', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd7089e76-3909-4879-88e2-5e2765a9d82b' User entered 'None (1)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:00
	System	18 Sep 2020 23:56:00

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:55:42', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd7089e76-3909-4879-88e2-5e2765a9d82b' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:00
	System	18 Sep 2020 23:56:00

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:55:46', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd7089e76-3909-4879-88e2-5e2765a9d82b' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:00
	System	18 Sep 2020 23:56:00

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:55:52', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd7089e76-3909-4879-88e2-5e2765a9d82b'	(b) (4), (b) (6)	18 Sep 2020 23:56:00
User entered 'None (1)'	System	18 Sep 2020 23:56:00

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:55:57', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd7089e76-3909-4879-88e2-5e2765a9d82b' User entered '18 Sep 2020 19:55'	(b) (4), (b) (6) System	18 Sep 2020 23:56:00
	System	18 Sep 2020 23:56:00

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 6'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c9e34024-ac2f-40d1-a041-aa0e3e83cccf' User entered 'None (1)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:32
	System	19 Sep 2020 20:09:32

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c9e34024-ac2f-40d1-a041-aa0e3e83cccf' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:32
	System	19 Sep 2020 20:09:32

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c9e34024-ac2f-40d1-a041-aa0e3e83cccf' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:32
	System	19 Sep 2020 20:09:32

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:27', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c9e34024-ac2f-40d1-a041-aa0e3e83cccf' User entered 'None (1)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:32
	System	19 Sep 2020 20:09:32

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c9e34024-ac2f-40d1-a041-aa0e3e83cccf' User entered '19 Sep 2020 16:09'	(b) (4), (b) (6) System	19 Sep 2020 20:09:32
	System	19 Sep 2020 20:09:32

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 7'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:07', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '13119c72-ada7-4e88-820d-ab8992594552'	(b) (4), (b) (6) System	20 Sep 2020 23:32:20
User entered 'None (1)'	System	20 Sep 2020 23:32:20

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '13119c72-ada7-4e88-820d-ab8992594552'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 23:32:20

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '13119c72-ada7-4e88-820d-ab8992594552'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 23:32:20

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:14', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '13119c72-ada7-4e88-820d-ab8992594552'	(b) (4), (b) (6) System	20 Sep 2020 23:32:20
User entered 'None (1)'	System	20 Sep 2020 23:32:20

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:17', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '13119c72-ada7-4e88-820d-ab8992594552'	(b) (4), (b) (6) System	20 Sep 2020 23:32:20
User entered '20 Sep 2020 19:32'	System	20 Sep 2020 23:32:20

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:14', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:17', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:19', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:29', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2' User entered 'No (N)'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-14T10:55:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'fe210a99-db50-4788-ab04-b434fc93aca2'	(b) (4), (b) (6) System	14 Sep 2020 14:55:43
User entered '14 Sep 2020 10:55'	System	14 Sep 2020 14:55:43

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 10:29'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 12:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:04', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:05', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:07', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T10:38:26', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '76f51254-2020-4b92-9c2a-6654ca02eb2c' User entered '15 Sep 2020 10:38'	(b) (4), (b) (6) System	15 Sep 2020 14:38:30
	System	15 Sep 2020 14:38:30

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '14 Sep 2020 13:54'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 2'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:27', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:33', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:36', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:38', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:40', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:45', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05'	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-15T23:21:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4b25debb-d5aa-483d-9240-739a52776d05'	(b) (4), (b) (6) System	16 Sep 2020 03:21:50
User entered '15 Sep 2020 23:21'	System	16 Sep 2020 03:21:50

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 3'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:11', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:14', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:16', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:19', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-16T18:22:27', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'c90a75e5-21b5-4d27-bf99-191d088b6f72' User entered '16 Sep 2020 18:22'	(b) (4), (b) (6) System	16 Sep 2020 22:22:29
	System	16 Sep 2020 22:22:29

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '16 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 4'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:06', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:08', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:13', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'None (0)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:18', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered 'No (N)'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-17T18:17:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1b8e2bc7-64a4-41f5-a0de-2dd322e6942c' User entered '17 Sep 2020 18:17'	(b) (4), (b) (6) System	17 Sep 2020 22:17:23
	System	17 Sep 2020 22:17:23

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '17 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 5'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:10', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:14', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:26', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'None (0)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:29', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered 'No (N)'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-18T19:56:36', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '0adda759-d28e-426a-93ac-2cdb3815b3da' User entered '18 Sep 2020 19:56'	(b) (4), (b) (6) System	18 Sep 2020 23:56:38
	System	18 Sep 2020 23:56:38

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 6'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:34', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:36', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:37', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:39', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:41', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:42', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'None (0)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:47', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered 'No (N)'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-19T16:09:51', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '42e55fce-ef5d-4ed2-bfeb-fb0a607422e5' User entered '19 Sep 2020 16:09'	(b) (4), (b) (6) System	19 Sep 2020 20:09:53
	System	19 Sep 2020 20:09:53

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	14 Sep 2020 14:12:12
User entered 'Day 7'	System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:22', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:27', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:29', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'None (0)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:32', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered 'No (N)'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-09-20T19:32:34', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2732d277-f60e-47aa-a910-b59e14d11aa9' User entered '20 Sep 2020 19:32'	(b) (4), (b) (6) System	20 Sep 2020 23:32:37
	System	20 Sep 2020 23:32:37

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:16:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	14 Sep 2020 14:12:12

US3242107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Grace Newville (b) (4)	24 Sep 2020 14:44:21
	(b) (4)	

US3242107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '24 Sep 2020'	Grace Newville (b) (4)	24 Sep 2020 14:44:21
	(b) (4)	

US3242107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	24 Sep 2020 14:44:21
	(b) (4)	

US3242107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Grace Newville (b) (4)	24 Sep 2020 14:44:21
	(b) (4)	

US3242107

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Grace Newville (b) (4)	24 Sep 2020 14:44:24
	(b) (4)	

US3242107

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 14:44:24
	System	

US3242107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Grace Newville (b) (4)	28 Sep 2020 17:07:15
	(b) (4)	

US3242107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '28 Sep 2020'	Grace Newville (b) (4)	28 Sep 2020 17:07:15
	(b) (4)	

US3242107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	28 Sep 2020 17:07:15
	(b) (4)	

US3242107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Grace Newville (b) (4)	28 Sep 2020 17:07:15
	(b) (4)	

US3242107

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Grace Newville (b) (4)	28 Sep 2020 17:07:18
	(b) (4)	

US3242107

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	System	28 Sep 2020 17:07:18

US3242107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Oct 2020 17:37:30
	(b) (4)	

US3242107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '5 Oct 2020'	Erynn McKinley (b) (4)	05 Oct 2020 17:37:30
	(b) (4)	

US3242107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	05 Oct 2020 17:37:30
	(b) (4)	

US3242107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	05 Oct 2020 17:37:30
	(b) (4)	

US3242107

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Oct 2020 17:37:34
	(b) (4)	

US3242107

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	(b) (4), (b) (6) System	05 Oct 2020 17:37:34

US3242107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 14:02:09
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '13 Oct 2020'	Erynn McKinley (b) (4)	13 Oct 2020 14:02:09
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[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 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	13 Oct 2020 14:02:09
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
User entered 'VISIT3'	System	13 Oct 2020 14:02:09

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '13 Oct 2020'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User closed query 'Per CDM: Please review and provide 'Start time' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc).' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:18:42
Query 'Per CDM: Please review and provide 'Start time' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc).' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	21 Oct 2020 17:39:08
User entered '09:09' reason for change: Data Entry Error	Donna Toepfer (b) (4)	21 Oct 2020 17:39:02
User opened query 'Per CDM: Please review and provide 'Start time' using the 24HR clock (e.g, 08:00 hrs for 8am, 20:00 hrs for 8pm etc).' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:05:31
User entered '9:09'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User entered '13 Oct 2020 09:09'	System	21 Oct 2020 17:39:02
User entered '13 Oct 2020 9:09'	System	13 Oct 2020 14:03:06

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '97.0' F	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered empty.	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '72'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
User entered 'bpm'	System	13 Oct 2020 14:03:06

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '18'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
User entered 'breaths/min'	System	13 Oct 2020 14:03:06

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '124'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
User entered 'mmHg'	(b) (4), (b) (6) System	13 Oct 2020 14:03:06

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '80'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:06
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
User entered 'mmHg'	(b) (4), (b) (6) System	13 Oct 2020 14:03:06

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:11:47
	(b) (4), (b) (6)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'No (N)'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:12
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered empty.	Erynn McKinley (b) (4)	13 Oct 2020 14:03:12
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:24
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '13 Oct 2020'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:24
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered '9:28'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:24
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered '13 Oct 2020 9:28'	(b) (4), (b) (6)	13 Oct 2020 14:03:24
	System	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:43:16
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	13 Oct 2020 14:03:47
	(b) (4)	

US3242107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	System	13 Oct 2020 14:03:47

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 64'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-15T15:40:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b9835b3d-1627-4bff-906d-c1da7bc925a2'	(b) (4), (b) (6)	15 Oct 2020 19:41:14
User entered 'No (N)'	System	15 Oct 2020 19:41:14

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you been exposed to someone with 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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-15T15:40:46', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b9835b3d-1627-4bff-906d-c1da7bc925a2'	(b) (4), (b) (6)	15 Oct 2020 19:41:14
User entered 'No (N)'	System	15 Oct 2020 19:41:14

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-15T15:41:04', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b9835b3d-1627-4bff-906d-c1da7bc925a2' User entered '15 Oct 2020 15:41:04'	(b) (4), (b) (6) System	15 Oct 2020 19:41:14
	System	15 Oct 2020 19:41:14

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '15 Oct 2020 00:01'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '19 Oct 2020 23:59'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 71'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-22T10:40:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd5007d76-6c3b-426e-9794-bdf7d44a3575'	(b) (4), (b) (6)	22 Oct 2020 14:40:23
User entered 'No (N)'	System	22 Oct 2020 14:40:23

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-22T10:40:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd5007d76-6c3b-426e-9794-bdf7d44a3575'	(b) (4), (b) (6)	22 Oct 2020 14:40:23
User entered 'No (N)'	System	22 Oct 2020 14:40:23

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-22T10:40:19', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'd5007d76-6c3b-426e-9794-bdf7d44a3575' User entered '22 Oct 2020 10:40:19'	(b) (4), (b) (6) System	22 Oct 2020 14:40:23
	System	22 Oct 2020 14:40:23

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '22 Oct 2020 00:01'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '26 Oct 2020 23:59'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 78'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-29T13:13:05', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3cb240d6-724a-4a4b-86ee-fc01c8f98459' User entered 'No (N)'	(b) (4), (b) (6) System	29 Oct 2020 17:13:22
	System	29 Oct 2020 17:13:22

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-29T13:13:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3cb240d6-724a-4a4b-86ee-fc01c8f98459' User entered 'No (N)'	(b) (4), (b) (6) System	29 Oct 2020 17:13:22
	System	29 Oct 2020 17:13:22

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-10-29T13:13:13', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '3cb240d6-724a-4a4b-86ee-fc01c8f98459' User entered '29 Oct 2020 13:13:13'	(b) (4), (b) (6) System	29 Oct 2020 17:13:22
	System	29 Oct 2020 17:13:22

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '29 Oct 2020 00:01'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '02 Nov 2020 23:59'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 92'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-14T11:29:14', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'df031ce2-5ded-4c66-b554-14450f79a35d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Nov 2020 16:29:27
	System	14 Nov 2020 16:29:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you been exposed to someone with 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 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-14T11:29:17', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'df031ce2-5ded-4c66-b554-14450f79a35d' User entered 'No (N)'	(b) (4), (b) (6) System	14 Nov 2020 16:29:27
	System	14 Nov 2020 16:29:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-14T11:29:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'df031ce2-5ded-4c66-b554-14450f79a35d' User entered '14 Nov 2020 11:29:25'	(b) (4), (b) (6) System	14 Nov 2020 16:29:27
	System	14 Nov 2020 16:29:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '12 Nov 2020 00:01'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:18:19
	(b) (4), (b) (6)	
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '16 Nov 2020 23:59'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27
Data entry locked.	System	15 Aug 2020 16:17:53
User entered 'Day 99'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you been exposed to someone with 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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Please 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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Please 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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Please 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 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '19 Nov 2020 00:01'	System	15 Aug 2020 16:17:53

US3242107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:24:27
Data entry locked.	System	15 Aug 2020 16:17:53
User entered '23 Nov 2020 23:59'	System	15 Aug 2020 16:17:53

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-19T18:55:08', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '371de758-d339-4487-86e2-2d651464040f' User entered 'No (N)'	System	19 Nov 2020 23:55:26

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-19T18:55:11', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '371de758-d339-4487-86e2-2d651464040f'	System	19 Nov 2020 23:55:26
User entered 'No (N)'	System	19 Nov 2020 23:55:26

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-19T18:55:20', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '371de758-d339-4487-86e2-2d651464040f' User entered '19 Nov 2020 18:55:20'	System	19 Nov 2020 23:55:26
	System	19 Nov 2020 23:55:26

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-24T14:21:15', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60a4783e-d261-4b41-b140-dc3598288425' User entered 'No (N)'	System	24 Nov 2020 19:21:30

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-24T14:21:19', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60a4783e-d261-4b41-b140-dc3598288425'	System	24 Nov 2020 19:21:30
User entered 'No (N)'	System	24 Nov 2020 19:21:30

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-24T14:21:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '60a4783e-d261-4b41-b140-dc3598288425' User entered '24 Nov 2020 14:21:25'	System	24 Nov 2020 19:21:30

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-30T00:03:35', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '69602f5d-bec0-4779-9eda-d569139b6fdd' User entered 'No (N)'	System	30 Nov 2020 05:03:51

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-30T00:03:37', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '69602f5d-bec0-4779-9eda-d569139b6fdd' User entered 'No (N)'	System	30 Nov 2020 05:03:51
	System	30 Nov 2020 05:03:51

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-11-30T00:03:48', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '69602f5d-bec0-4779-9eda-d569139b6fdd' User entered '30 Nov 2020 00:03:48'	System	30 Nov 2020 05:03:51
	System	30 Nov 2020 05:03:51

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-08T10:01:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '8d7b93b2-03e7-43f5-898c-44543dff69a3' User entered 'No (N)'	System	08 Dec 2020 15:01:42
	System	08 Dec 2020 15:01:42

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-08T10:01:34', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '8d7b93b2-03e7-43f5-898c-44543dff69a3'	System	08 Dec 2020 15:01:42
User entered 'No (N)'	System	08 Dec 2020 15:01:42

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-08T10:01:38', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '8d7b93b2-03e7-43f5-898c-44543dff69a3' User entered '08 Dec 2020 10:01:38'	System	08 Dec 2020 15:01:42
	System	08 Dec 2020 15:01:42

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-14T09:52:18', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '20f123c2-6296-4735-8bda-0aec7d2ee72a' User entered 'No (N)'	System	14 Dec 2020 14:52:29
	System	14 Dec 2020 14:52:29

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-14T09:52:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '20f123c2-6296-4735-8bda-0aec7d2ee72a' User entered 'No (N)'	System	14 Dec 2020 14:52:29
	System	14 Dec 2020 14:52:29

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-14T09:52:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '20f123c2-6296-4735-8bda-0aec7d2ee72a' User entered '14 Dec 2020 09:52:24'	System	14 Dec 2020 14:52:29
	System	14 Dec 2020 14:52:29

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-21T10:46:57', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'f2a344a7-da3e-47b0-89e6-7c69d799aaf2'	System	21 Dec 2020 15:47:06
User entered 'No (N)'	System	21 Dec 2020 15:47:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-21T10:46:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'f2a344a7-da3e-47b0-89e6-7c69d799aaf2'	System	21 Dec 2020 15:47:06
User entered 'No (N)'	System	21 Dec 2020 15:47:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-21T10:47:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'f2a344a7-da3e-47b0-89e6-7c69d799aaf2' User entered '21 Dec 2020 10:47:02'	System	21 Dec 2020 15:47:06
	System	21 Dec 2020 15:47:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-29T09:18:28', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9d16bda1-c9fe-4d83-acee-61da5ddb27a6'	System	29 Dec 2020 14:18:36
User entered 'No (N)'	System	29 Dec 2020 14:18:36

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-29T09:18:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9d16bda1-c9fe-4d83-acee-61da5ddb27a6'	System	29 Dec 2020 14:18:36
User entered 'No (N)'	System	29 Dec 2020 14:18:36

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2020-12-29T09:18:33', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '9d16bda1-c9fe-4d83-acee-61da5ddb27a6' User entered '29 Dec 2020 09:18:33'	System	29 Dec 2020 14:18:36
	System	29 Dec 2020 14:18:36

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-04T08:27:24', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4ddaa172-56eb-41f6-ac58-9ec1aa40622b' User entered 'No (N)'	System	04 Jan 2021 13:27:32
	System	04 Jan 2021 13:27:32

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-04T08:27:26', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4ddaa172-56eb-41f6-ac58-9ec1aa40622b' User entered 'No (N)'	System	04 Jan 2021 13:27:32

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-04T08:27:30', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '4ddaa172-56eb-41f6-ac58-9ec1aa40622b' User entered '04 Jan 2021 08:27:30'	System	04 Jan 2021 13:27:32
	System	04 Jan 2021 13:27:32

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-11T03:02:25', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a4ac3301-a9b3-42c3-94b5-c244f70f3149' User entered 'Yes (Y)'	System	11 Jan 2021 08:03:34
	System	11 Jan 2021 08:03:34

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-11T03:02:33', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a4ac3301-a9b3-42c3-94b5-c244f70f3149'	System	11 Jan 2021 08:03:34
User entered 'No (N)'	System	11 Jan 2021 08:03:34

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-11T03:02:40', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a4ac3301-a9b3-42c3-94b5-c244f70f3149'	System	11 Jan 2021 08:03:34
User entered 'No (N)'	System	11 Jan 2021 08:03:34

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-11T03:02:54', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a4ac3301-a9b3-42c3-94b5-c244f70f3149'	System	11 Jan 2021 08:03:34
User entered 'Yes (Y)'	System	11 Jan 2021 08:03:34

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-11T03:03:09', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a4ac3301-a9b3-42c3-94b5-c244f70f3149'	System	11 Jan 2021 08:03:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Jan 2021 08:03:34

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-11T03:03:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a4ac3301-a9b3-42c3-94b5-c244f70f3149' User entered '11 Jan 2021 03:03:23'	System	11 Jan 2021 08:03:34
	System	11 Jan 2021 08:03:34

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-20T14:18:05', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1ce2787b-e525-4ec2-9991-71000126819d' User entered 'No (N)'	System	20 Jan 2021 19:18:14
	System	20 Jan 2021 19:18:14

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-20T14:18:08', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1ce2787b-e525-4ec2-9991-71000126819d' User entered 'No (N)'	System	20 Jan 2021 19:18:14

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-20T14:18:12', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '1ce2787b-e525-4ec2-9991-71000126819d' User entered '20 Jan 2021 14:18:12'	System	20 Jan 2021 19:18:14
	System	20 Jan 2021 19:18:14

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-25T08:56:21', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2305a0f3-5914-43a1-81dd-9496cb8e9bff'	System	25 Jan 2021 13:56:38
User entered 'No (N)'	System	25 Jan 2021 13:56:38

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-25T08:56:23', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2305a0f3-5914-43a1-81dd-9496cb8e9bff'	System	25 Jan 2021 13:56:38
User entered 'No (N)'	System	25 Jan 2021 13:56:38

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-01-25T08:56:34', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2305a0f3-5914-43a1-81dd-9496cb8e9bff' User entered '25 Jan 2021 08:56:34'	System	25 Jan 2021 13:56:38
	System	25 Jan 2021 13:56:38

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-03T09:10:56', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a89afebc-8c02-48ae-a7a6-b6cfff3b5ddc' User entered 'No (N)'	System	03 Feb 2021 14:11:06
	System	03 Feb 2021 14:11:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-03T09:10:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a89afebc-8c02-48ae-a7a6-b6cfff3b5ddc' User entered 'No (N)'	System	03 Feb 2021 14:11:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-03T09:11:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'a89afebc-8c02-48ae-a7a6-b6cfff3b5ddc' User entered '03 Feb 2021 09:11:02'	System	03 Feb 2021 14:11:06
	System	03 Feb 2021 14:11:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-08T09:57:54', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '86827a65-96e5-4039-b63e-e09945132f6e' User entered 'No (N)'	System	08 Feb 2021 14:58:03
	System	08 Feb 2021 14:58:03

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-08T09:57:56', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '86827a65-96e5-4039-b63e-e09945132f6e' User entered 'No (N)'	System	08 Feb 2021 14:58:03

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-08T09:57:59', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '86827a65-96e5-4039-b63e-e09945132f6e' User entered '08 Feb 2021 09:57:59'	System	08 Feb 2021 14:58:03
	System	08 Feb 2021 14:58:03

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-15T10:29:51', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '11959929-41b8-44ac-be2e-73a11a0c592c' User entered 'No (N)'	System	15 Feb 2021 15:30:06
	System	15 Feb 2021 15:30:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-15T10:29:53', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '11959929-41b8-44ac-be2e-73a11a0c592c' User entered 'No (N)'	System	15 Feb 2021 15:30:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-15T10:30:02', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '11959929-41b8-44ac-be2e-73a11a0c592c' User entered '15 Feb 2021 10:30:02'	System	15 Feb 2021 15:30:06
	System	15 Feb 2021 15:30:06

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-24T12:00:47-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7c4f44d2-c409-47b7-b059-1ac72bbc41fb' User entered 'No (N)'	System	24 Feb 2021 17:03:13
	System	24 Feb 2021 17:03:13

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-24T12:00:49-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7c4f44d2-c409-47b7-b059-1ac72bbc41fb' User entered 'No (N)'	System	24 Feb 2021 17:03:13

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-02-24T12:00:52-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '7c4f44d2-c409-47b7-b059-1ac72bbc41fb' User entered '24 Feb 2021 17:00:52'	System	24 Feb 2021 17:03:13
	System	24 Feb 2021 17:03:13

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-01T07:58:36-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b92691f4-ad23-418d-b71a-ecaaa51ad18f'	System	01 Mar 2021 12:58:47
User entered 'No (N)'	System	01 Mar 2021 12:58:47

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-01T07:58:39-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b92691f4-ad23-418d-b71a-ecaaa51ad18f'	System	01 Mar 2021 12:58:47
User entered 'No (N)'	System	01 Mar 2021 12:58:47

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-01T07:58:46-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'b92691f4-ad23-418d-b71a-ecaaa51ad18f'	System	01 Mar 2021 12:58:47
User entered '01 Mar 2021 07:58:46'	System	01 Mar 2021 12:58:47

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-08T00:40:50-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2dc338-75be-4125-867c-4647b170deff'	System	08 Mar 2021 05:40:57
User entered 'No (N)'	System	08 Mar 2021 05:40:57

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-08T00:40:52-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2dc338-75be-4125-867c-4647b170deff'	System	08 Mar 2021 05:40:57
User entered 'No (N)'	System	08 Mar 2021 05:40:57

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-08T00:40:55-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '2dc338-75be-4125-867c-4647b170deff' User entered '08 Mar 2021 00:40:55'	System	08 Mar 2021 05:40:57
	System	08 Mar 2021 05:40:57

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-15T22:15:09-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6899f11d-73d5-4ebc-955d-1acc3f6843a6'	System	16 Mar 2021 02:15:18
User entered 'No (N)'	System	16 Mar 2021 02:15:18

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-15T22:15:11-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6899f11d-73d5-4ebc-955d-1acc3f6843a6'	System	16 Mar 2021 02:15:18
User entered 'No (N)'	System	16 Mar 2021 02:15:18

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-15T22:15:14-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '6899f11d-73d5-4ebc-955d-1acc3f6843a6' User entered '15 Mar 2021 22:15:14'	System	16 Mar 2021 02:15:18
	System	16 Mar 2021 02:15:18

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-22T09:06:33-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'e2d1ccdc-4ecb-4373-b7f4-c9192020a0b0'	System	22 Mar 2021 13:06:42
User entered 'No (N)'	System	22 Mar 2021 13:06:42

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-22T09:06:35-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'e2d1ccdc-4ecb-4373-b7f4-c9192020a0b0'	System	22 Mar 2021 13:06:42
User entered 'No (N)'	System	22 Mar 2021 13:06:42

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-22T09:06:38-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'e2d1ccdc-4ecb-4373-b7f4-c9192020a0b0'	System	22 Mar 2021 13:06:42
User entered '22 Mar 2021 09:06:38'	System	22 Mar 2021 13:06:42

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-29T05:25:16-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '571b07df-839d-4a1a-99ff-429d2c611ed7'	System	29 Mar 2021 09:25:25
User entered 'No (N)'	System	29 Mar 2021 09:25:25

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-29T05:25:18-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '571b07df-839d-4a1a-99ff-429d2c611ed7'	System	29 Mar 2021 09:25:25
User entered 'No (N)'	System	29 Mar 2021 09:25:25

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-29T05:25:22-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '571b07df-839d-4a1a-99ff-429d2c611ed7' User entered '29 Mar 2021 05:25:22'	System	29 Mar 2021 09:25:25
	System	29 Mar 2021 09:25:25

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-08T14:12:15-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '64c2d671-ec2a-4d1e-a0fe-2c0f3cda41db' User entered 'No (N)'	System	08 Apr 2021 18:12:29

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-08T14:12:17-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '64c2d671-ec2a-4d1e-a0fe-2c0f3cda41db' User entered 'No (N)'	System	08 Apr 2021 18:12:29

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-08T14:12:21-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '64c2d671-ec2a-4d1e-a0fe-2c0f3cda41db' User entered '08 Apr 2021 14:12:21'	System	08 Apr 2021 18:12:29
	System	08 Apr 2021 18:12:29

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-12T09:16:26-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'f6739c05-a149-4272-bb3d-fa94bbb8449e' User entered 'No (N)'	System	12 Apr 2021 13:16:48
	System	12 Apr 2021 13:16:48

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-12T09:16:30-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'f6739c05-a149-4272-bb3d-fa94bbb8449e'	System	12 Apr 2021 13:16:48
User entered 'No (N)'	System	12 Apr 2021 13:16:48

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-12T09:16:33-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'f6739c05-a149-4272-bb3d-fa94bbb8449e' User entered '12 Apr 2021 09:16:33'	System	12 Apr 2021 13:16:48
	System	12 Apr 2021 13:16:48

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-20T15:11:31-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '16935f52-4318-4f4e-b74e-0d1220492786'	System	20 Apr 2021 19:11:40
User entered 'No (N)'	System	20 Apr 2021 19:11:40

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-20T15:11:33-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '16935f52-4318-4f4e-b74e-0d1220492786'	System	20 Apr 2021 19:11:40
User entered 'No (N)'	System	20 Apr 2021 19:11:40

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-20T15:11:36-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '16935f52-4318-4f4e-b74e-0d1220492786'	System	20 Apr 2021 19:11:40
User entered '20 Apr 2021 15:11:36'	System	20 Apr 2021 19:11:40

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-26T09:19:56-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '21b3b0c5-78ec-4d3a-bd8d-eeabc562d658' User entered 'No (N)'	System	26 Apr 2021 13:20:05
	System	26 Apr 2021 13:20:05

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-26T09:19:58-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '21b3b0c5-78ec-4d3a-bd8d-eeabc562d658' User entered 'No (N)'	System	26 Apr 2021 13:20:05
	System	26 Apr 2021 13:20:05

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-04-26T09:20:01-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '21b3b0c5-78ec-4d3a-bd8d-eeabc562d658'	System	26 Apr 2021 13:20:05
User entered '26 Apr 2021 09:20:01'	System	26 Apr 2021 13:20:05

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-05-03T12:34:57-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '43549353-9b3c-4308-b8ac-e2e4d125a0bb' User entered 'No (N)'	System	03 May 2021 16:35:10
	System	03 May 2021 16:35:10

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

Have you been exposed to someone with 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 (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-05-03T12:34:59-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '43549353-9b3c-4308-b8ac-e2e4d125a0bb'	System	03 May 2021 16:35:10
User entered 'No (N)'	System	03 May 2021 16:35:10

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-05-03T12:35:02-04:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: '43549353-9b3c-4308-b8ac-e2e4d125a0bb'	System	03 May 2021 16:35:10
User entered '03 May 2021 12:35:02'	System	03 May 2021 16:35:10

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 08:24:27

US3242107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:16:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:24:27
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 08:24:27

US3242107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:16:00

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 07:41:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-01T07:59:00-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'bd88f612-5a4e-40f0-a185-da6ff755b58b'	(b) (4), (b) (6)	01 Mar 2021 12:59:10
User entered 'No (N)'	System	01 Mar 2021 12:59:10

US3242107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:16:00

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A78F370C-ACA1-48F6-A314-556E5A27FDD9)', Time: '2021-03-01T07:59:07-05:00', User OID: 'PatientReportedOutcome (US3242107)', ODM File OID: 'bd88f612-5a4e-40f0-a185-da6ff755b58b' User entered '01 Mar 2021 07:59:07'	(b) (4), (b) (6) System	01 Mar 2021 12:59:10
	System	01 Mar 2021 12:59:10

US3242107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:03
	(b) (4)	

US3242107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Dec 2020 20:23:21
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	10 Dec 2020 20:23:21
User entered '9 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	10 Dec 2020 20:23:21
	(b) (4)	
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Dec 2020 20:23:03
User entered '9 Dec 2020'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:03
	(b) (4)	

US3242107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:03
	(b) (4)	

US3242107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	10 Dec 2020 20:23:03
	(b) (4)	

US3242107

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:25
	(b) (4)	

US3242107

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:10:27
User entered 'I'	System	10 Dec 2020 20:23:25

US3242107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:40
	(b) (4)	

US3242107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '10 Dec 2020'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:40
	(b) (4)	

US3242107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:40
	(b) (4)	

US3242107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	10 Dec 2020 20:23:40
	(b) (4)	

US3242107

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	10 Dec 2020 20:23:47
	(b) (4)	

US3242107

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered 'I'	(b) (4), (b) (6) System	10 Dec 2020 20:23:47

US3242107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 20:40:02
	(b) (4)	

US3242107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '11 Jan 2021'	Erynn McKinley (b) (4)	14 Jan 2021 20:40:02
	(b) (4)	

US3242107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	14 Jan 2021 20:40:02
	(b) (4)	

US3242107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	14 Jan 2021 20:40:02
	(b) (4)	

US3242107

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	14 Jan 2021 20:40:06
	(b) (4)	

US3242107

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered 'I'	(b) (4), (b) (6) System	14 Jan 2021 20:40:06

US3242107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Feb 2021 19:23:27
	(b) (4)	

US3242107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '8 Feb 2021'	Erynn McKinley (b) (4)	08 Feb 2021 19:23:27
	(b) (4)	

US3242107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	08 Feb 2021 19:23:27
	(b) (4)	

US3242107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered empty.	Erynn McKinley (b) (4)	08 Feb 2021 19:23:27
	(b) (4)	

US3242107

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	08 Feb 2021 19:23:33
	(b) (4)	

US3242107

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered 'I'	(b) (4), (b) (6) System	08 Feb 2021 19:23:33

US3242107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:43
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered '23 Mar 2021'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:43
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[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 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:43
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered 'VISIT4'	(b) (4), (b) (6) System	23 Mar 2021 13:56:43

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:23:05

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:23:05

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:23:05

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:23:05

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:43:22
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:23:05
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:23:05

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:02:34

US3242107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:16:00

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:02:34

US3242107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered 'No (N)'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:50
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:16:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered empty.	Erynn McKinley (b) (4)	23 Mar 2021 13:56:50
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:57
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under Visit 4 Day 209 is dated 23MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:14:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under Visit 4 Day 209 is dated 23MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'Req 1F636133923 shipped 3/30/21 fed ex 945470637115' (Site from DM).	Susan Jones (b) (4)	08 Apr 2021 17:53:38
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per Preclarus report, Sample recorded under Visit 4 Day 209 is dated 23MAR2021 is in EDC, however the same is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:45:46
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered '23 Mar 2021'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:57

US3242107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered '09:28'	Erynn McKinley (b) (4)	23 Mar 2021 13:56:57
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered '23 Mar 2021 09:28'	(b) (4), (b) (6) System	23 Mar 2021 13:56:57

US3242107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:11:27
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Mar 2021 13:57:00
	(b) (4)	

US3242107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:02:34
User entered 'I'	(b) (4), (b) (6) System	23 Mar 2021 13:57:00

US3242107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:02:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:28:47

US3242107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:02:27
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:28:47

US3242107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:02:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:28:47

US3242107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:16:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:02:27
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:28:47

US3242107

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	13 Apr 2021 13:02:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 23:28:37

US3242107

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:16:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 23:28:37

US3242107

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

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 16:12:54

US3242107

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

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 16:12:54

US3242107

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

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	19 Jan 2021 16:12:54

US3242107

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

Form: Visit Date

Generated On: 09 Jun 2021 16:16:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	19 Jan 2021 16:12:54

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:36:58
	(b) (4)	
User entered '0'	Donna Toepfer (b) (4)	22 Apr 2021 15:20:01
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:10:39

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 15:32:25
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Jon Finley (b) (4) (b) (4)	22 Apr 2021 16:36:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	Donna Toepfer (b) (4)	22 Apr 2021 15:20:27
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	(b) (4), (b) (6) System	22 Apr 2021 08:08:46 06 Mar 2021 05:10:39

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:21:45
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:21:45
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered empty.	(b) (4), (b) (6) System	19 Jan 2021 16:13:12

US3242107

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

Form: Unblinding

Generated On: 09 Jun 2021 16:16:00

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered empty.	(b) (4), (b) (6) System	19 Jan 2021 16:13:12

US3242107

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:25

US3242107

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:25

US3242107

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '10:13'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:25

US3242107

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:16:00

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '19 Jan 2021 10:13'	(b) (4), (b) (6) System	19 Jan 2021 16:13:25

US3242107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:16:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:37

US3242107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:37

US3242107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:16:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '09:58'	Donna Toepfer (b) (4)	19 Jan 2021 16:13:37

US3242107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:16:00

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:45:43
User entered '19 Jan 2021 09:58'	(b) (4), (b) (6) System	19 Jan 2021 16:13:37

US3242107

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:16:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:40
	(b) (4), (b) (6)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	13 Jan 2021 15:33:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Jan 2021 15:33:02
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:29:45

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:51
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:56:57
User entered	System	13 Jan 2021 23:56:12
'USA-US067-2021-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	13 Jan 2021 23:56:12

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please specify this AE if possible, such as ischemic stroke, embolism, hemorrhagic stroke or subarachnoid hemorrhage, et al. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 09:08:21
Query 'Per MM: Please specify this AE if possible, such as ischemic stroke, embolism, hemorrhagic stroke or subarachnoid hemorrhage, et al. ' answered with 'this is per med records' (Site from DM).	Donna Toepfer (b) (4)	17 Feb 2021 13:40:17
User opened query 'Per MM: Please specify this AE if possible, such as ischemic stroke, embolism, hemorrhagic stroke or subarachnoid hemorrhage, et al. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 15:58:53
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:51
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\23.0.	(b) (4), (b) (6) Coder Import (b) (4)	13 Jan 2021 15:40:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Jan 2021 15:40:02
Data point term sent to Coder	System	13 Jan 2021 15:38:48
User entered 'Cerebrovascular accident'	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:51
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '09 Jan 2021'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Jan 2021 15:44:30
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:44:30
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	13 Jan 2021 15:44:11
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
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	13 Jan 2021 15:44:50
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	13 Jan 2021 15:44:50
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	13 Jan 2021 15:44:11
User entered '09 Jan 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:44:11
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 15:54:35
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 'has not been discharged' (Site from System).	Donna Toepfer (b) (4)	13 Jan 2021 15:38:34
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	13 Jan 2021 15:37:59
User entered 'I'	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '09 Jan 2020'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 14:40:52
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'subject remained for observation' (Site from Safety).	Donna Toepfer (b) (4)	12 Feb 2021 13:40:23
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:56:30
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	13 Jan 2021 15:49:02
User entered empty.	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Jan 2021 15:38:17
User entered empty.	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'Not Applicable (NOT APPLICABLE)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed #s 5 and 6 were given after the End date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:28:38
Query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed #s 5 and 6 were given after the End date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'yes, they were given as a result of the CVA' (Site from DM).	Donna Toepfer (b) (4)	16 Feb 2021 14:06:22
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed #s 5 and 6 were given after the End date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:20:48
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:51
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 18:44:01
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	25 Jan 2021 16:50:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered 'I'	(b) (4), (b) (6) [REDACTED]	24 Jan 2021 12:05:22
	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Jan 2021 15:44:50
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:51
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:37:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:44:29
User closed query 'Per DM CLR: Narrative indicates that subject had "CTA HEAD/NECK, MRI, ECHO." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:25:42
Query 'Per DM CLR: Narrative indicates that subject had "CTA HEAD/NECK, MRI, ECHO." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	02 Mar 2021 14:55:59
User opened query 'Per DM CLR: Narrative indicates that subject had "CTA HEAD/NECK, MRI, ECHO." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:58:31
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
User closed query 'PV Query: Please confirm results of D dimer and computed tomography angiography pulmonary embolism (CTA PE).' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 14:41:06
Query 'PV Query: Please confirm results of D dimer and computed tomography angiography pulmonary embolism (CTA PE).' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	12 Feb 2021 14:02:27
Signature has been broken.	Donna Toepfer (b) (4)	12 Feb 2021 13:58:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED TO HOSPITAL WITH CVA 1/9/2021, TREATED, NO RESIDUAL BY HISTORY THOUGH REMAINS IN HOSPITAL FOR OBSERVATION. UPDATE, DISCHARGED ON THE 12 JAN 2021. SAR COV-2 TEST, FLU A, FLU B, RSV DONE ON 1/9/2021-ALL NEGATIVE CTA head/neck showed no large vessel disease and MRI showed subacute left mca lacunar stroke. Echo showed no PFO and no additional therapy needed.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	12 Feb 2021 13:58:16
User opened query 'PV Query: Please confirm results of D dimer and computed tomography angiography pulmonary embolism (CTA PE).' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:54:56
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
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)	05 Feb 2021 18:19:33
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 18:19:29
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 'sent today 2/4/21' (Site from Safety).	Donna Toepfer (b) (4)	04 Feb 2021 14:30:40
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	04 Feb 2021 13:34:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Donna Toepfer (b) (4)	04 Feb 2021 13:33:53
User entered 'ADMITTED TO HOSPITAL WITH CVA 1/9/2021, TREATED, NO RESIDUAL BY HISTORY THOUGH REMAINS IN HOSPITAL FOR OBSERVATION. UPDATE, DISCHARGED ON THE 12 JAN 2021. SAR COV-2 test, Flu A, Flu B, RSV done on 1/9/2021-all negative' reason for change: Data Entry Error	Donna Toepfer (b) (4)	04 Feb 2021 13:33:53
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)	03 Feb 2021 16:48:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 16:48:25
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:51
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 19:06:06
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)	26 Jan 2021 19:05:58
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 19:05:42

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Folder: Adverse Events

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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 'coordinator to send discharge summary to safety' (Site from Safety).	Donna Toepfer (b) (4)	25 Jan 2021 16:59:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'no relevant test results' (Site from Safety).	Donna Toepfer (b) (4)	25 Jan 2021 16:58:45
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No results for Covid-19' (Site from Safety).	Donna Toepfer (b) (4)	25 Jan 2021 16:57:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:50:29
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)	22 Jan 2021 16:50:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:49:59

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED TO HOSPITAL WITH CVA 1/9/2021, TREATED, NO RESIDUAL BY HISTORY THOUGH REMAINS IN HOSPITAL FOR OBSERVATION. update, discharged on the 12 Jan 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	13 Jan 2021 15:49:02
User entered 'Admitted to hospital with CVA 1/9/2021, treated, no residual by history though remains in hospital for observation'	Donna Toepfer (b) (4)	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Jan 2021 15:37:59

US3242107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:16:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Jan 2021 15:38:17

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:16:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:18
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Aug 2020 17:25:58

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 17:31:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 17:31:25
Data point term sent to Coder	System	15 Aug 2020 17:30:48
User entered 'Omeprazole'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered '20'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'mg (mg)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
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)	15 Aug 2020 21:33:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Donna Toepfer (b) (4)	15 Aug 2020 17:30:36
answered with 'correct per protocol' (Site from System).		
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	15 Aug 2020 17:30:30
User entered '01 Jan 1998'	Donna Toepfer (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered '0'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 17:30:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 17:33:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 17:33:25
Data point term sent to Coder	System	15 Aug 2020 17:31:51
User entered 'Multivitamin'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 18:42:23
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) Donna Toepfer (b) (4)	27 Jan 2021 15:45:10 26 Jan 2021 19:45:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	26 Jan 2021 19:45:28
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Jan 2021 18:43:41 14 Nov 2020 03:28:49
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Diet Supplement'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'I'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'tablet (TABLET)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
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)	15 Aug 2020 21:33:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct per protocol' (Site from System).	Donna Toepfer (b) (4)	15 Aug 2020 17:31:19
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	15 Aug 2020 17:31:14
User entered '01 Jan 2008'	Donna Toepfer (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered '0'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered empty.	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Nov 2020 03:28:49
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 17:31:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 15:10:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 15:10:57
Data point term sent to Coder	System	14 Dec 2020 15:10:12
User entered 'Influenza Vaccine'	Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Yes (Y)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Prophylaxis for Influenza'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '0.5'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'mL (mL)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'once (ONCE)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4) (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '10 Oct 2020'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '0'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'No (N)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '10 Oct 2020'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'No (N)'	(b) (4), (b) (6) Erynn McKinley (b) (4)	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:05:17
User entered empty.	(b) (4), (b) (6) System	14 Dec 2020 15:09:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:48:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:48:01
Data point term sent to Coder	System	13 Jan 2021 15:47:02
User entered 'Lipitor'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Hyperlipidemia'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '40'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'mg (mg)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
	(b) (4)	
User closed query 'Per DM CLR: Con Med LIPITOR was added/changed on 10 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 17:09:23
Query 'Per DM CLR: Con Med LIPITOR was added/changed on 10 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'not a worsening. subject stopped taking meds previously and now has started back' (Site from DM).	Donna Toepfer (b) (4)	05 Feb 2021 14:53:53
User opened query 'Per DM CLR: Con Med LIPITOR was added/changed on 10 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:35:38
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '10 Jan 2021'	(b) (4), (b) (6)	
	Donna Toepfer (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:46:30

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:28:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:28:53
Data point term sent to Coder	System	18 Feb 2021 13:43:08
Coding entries removed.	Donna Toepfer (b) (4)	18 Feb 2021 13:42:08
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:51:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:51:57
Data point term sent to Coder	System	25 Jan 2021 16:51:08
Coding entries removed.	Donna Toepfer (b) (4)	25 Jan 2021 16:51:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:52:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:52:01
Data point term sent to Coder	System	13 Jan 2021 15:48:02
User entered 'Aspirin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:22:52
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	18 Feb 2021 13:42:14
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:52:23
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Yes (Y)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	19 Feb 2021 14:50:48
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	18 Feb 2021 13:42:08
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Feb 2021 13:42:08
User entered 'Post CEREBROVASCULAR ACCIDENT, prophylaxis for heart health' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Feb 2021 13:42:08
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Cerebrovascular Accident' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	25 Jan 2021 16:51:02
User entered 'Heart health/Post CVA'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '81'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'mg (mg)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '10 Jan 2021'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:47:14

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:35:02
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 Feb 2021 22:35:02
Data point term sent to Coder	System	18 Feb 2021 13:43:10
Coding entries removed.	Donna Toepfer (b) (4) (b) (4) (b) (4)	18 Feb 2021 13:42:45
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 16:52:48
Data point term sent to Coder	System	25 Jan 2021 16:52:09
Coding entries removed.	Donna Toepfer (b) (4) (b) (4) (b) (4)	25 Jan 2021 16:51:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 14:55:55

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Jan 2021 14:55:55
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	13 Jan 2021 15:55:05
User entered 'Clopidogrel'	Donna Toepfer (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:23:08
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	18 Feb 2021 13:42:51
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:52:31
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Yes (Y)'	(b) (4), (b) (6) Donna Toepfer (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	19 Feb 2021 14:50:48
DataPoint Un-verified.	Donna Toepfer (b) (4) (b) (4)	18 Feb 2021 13:42:45
Signature has been broken.	Donna Toepfer (b) (4) (b) (4)	18 Feb 2021 13:42:45
User entered 'Post CEREBROVASCULAR ACCIDENT, prophylaxis for heart health' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	18 Feb 2021 13:42:45
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Cerebrovascular Accident' reason for change: Data Entry Error	Donna Toepfer (b) (4) (b) (4)	25 Jan 2021 16:51:21
User entered 'Prophylaxis/Post CVA'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '75'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'mg (mg)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'once daily (QD)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '12 Jan 2021'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered '0'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered empty.	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:45:10
User entered 'No (N)'	Donna Toepfer (b) (4) (b) (4)	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:55:02

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 21:55:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 21:55:57
Data point term sent to Coder	System	18 Feb 2021 18:25:20
User entered 'Alteplase'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Sliding Scale'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mg/kg'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:24:25
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:07:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:24:25

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
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: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:14:57
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 Apr 2021 16:14:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:08:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:08:42
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	19 Feb 2021 14:50:48
Data point term sent to Coder	System	18 Feb 2021 18:26:21
User entered 'Sodium Chloride 9%'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0.81'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mL/kg/hr'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 18:25:51
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:12:27
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:25:51

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:21:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:21:45
Data point term sent to Coder	System	18 Feb 2021 18:27:25
User entered 'Iopamidol 76%'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '100'	Erynn McKinley (b) (4)	18 Feb 2021 18:27:08
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mL (mL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:27:08
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:27:08
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:27:08
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 18:27:08
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 18:27:08
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:08:23
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:27:08

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
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)	18 Feb 2021 18:29:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:29:53
Data point term sent to Coder	System	18 Feb 2021 18:28:29
User entered 'Acetaminophen'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '650'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:27:59
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:22
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:27:59

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: ALUMINIUM HYDROXIDE/MAGNESIUM HYDROXIDE/SIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:04:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:04:59
Data point term sent to Coder	System	18 Feb 2021 18:30:32
User entered 'Aluminum Magnesium Hydroxide Simethicone'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 18:29:35
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '30'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mL (mL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:29:35
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:29:35
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:09:43
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:29:35

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 21:11:02
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 Feb 2021 21:11:02
Data point term sent to Coder	System	18 Feb 2021 18:31:34
User entered 'Aspirin'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '325'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:02
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:30:42

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 23:36:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 23:36:58
	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 18:31:33
User entered 'Dextrose'	Erynn McKinley (b) (4)	18 Feb 2021 18:31:31
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '20'	Erynn McKinley (b) (4)	18 Feb 2021 18:31:31
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'g (g)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:31:31
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4)	18 Feb 2021 18:31:31
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:16
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:31:31

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:41:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	16 Mar 2021 11:41:52
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
Data point term sent to Coder	System	18 Feb 2021 18:32:34
User entered 'Methylprednisolone Sodium Succ'	Erynn McKinley (b) (4)	18 Feb 2021 18:32:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '125'	Erynn McKinley (b) (4)	18 Feb 2021 18:32:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:32:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 18:32:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:35
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:32:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:20:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:20:46
Data point term sent to Coder	System	18 Feb 2021 18:33:35
User entered 'Insulin Lispro'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Sliding Scale'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Units'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:10:50
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:33:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, PRODUCT: CALCIUM GLUCONATE;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:15:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:15:56
Data point term sent to Coder	System	18 Feb 2021 18:34:35
User entered 'Calcium Gluconate in 9% Sodium Chloride'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'I'	Erynn McKinley (b) (4)	18 Feb 2021 18:34:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'g (g)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:34:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
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). 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	18 Feb 2021 18:35:12
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). User entered 'once (ONCE)'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:34:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 18:34:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '09 Jan 2021' reason for change: Data Entry Error	Erynn McKinley (b) (4)	18 Feb 2021 18:35:12
	(b) (4)	
User entered '12 Jan 2021'	Erynn McKinley (b) (4)	18 Feb 2021 18:34:29
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:06
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:34:29

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
	(b) (4), (b) (6)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 17:50:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 17:50:51
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
Data point term sent to Coder	System	18 Feb 2021 18:36:40
User entered 'Heparin'	Erynn McKinley (b) (4)	18 Feb 2021 18:36:07
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '5000'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Units'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '11 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '12 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:47
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:36:07

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
	(b) (4), (b) (6)	
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: ULTRASOUND CONTRAST MEDIA, ATC: ULTRASOUND CONTRAST MEDIA, PRODUCT: PERFLUTREN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 10:21:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 10:21:37
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
Data point term sent to Coder	System	18 Feb 2021 18:37:41
User entered 'Perflutren Lipid Microshperes'	Erynn McKinley (b) (4)	18 Feb 2021 18:37:20
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Cerebral Vascular Accident'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '5'	Erynn McKinley (b) (4)	18 Feb 2021 18:37:20
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'mL (mL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 18:37:20
	(b) (4)	

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '11 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered '11 Jan 2021'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	19 Feb 2021 14:50:48
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:16:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:11:53
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 18:37:20

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:16:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:02:47
DataPoint Un-verified.	Donna Toepfer (b) (4)	02 Mar 2021 14:54:45
Signature has been broken.	Donna Toepfer (b) (4)	02 Mar 2021 14:54:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	02 Mar 2021 14:54:45
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 03:28:49
	(b) (4), (b) (6)	
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Aug 2020 16:41:14

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:16:00

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered '09 Jan 2021'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:04

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:16:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered 'Echo'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:04

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:04

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:16:00

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered empty.	Donna Toepfer (b) (4)	02 Mar 2021 14:55:04

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:16:00

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered '09 Jan 2021'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:28

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:16:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered 'CT/Head and Neck'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:28

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:28

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:16:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered empty.	Donna Toepfer (b) (4)	02 Mar 2021 14:55:28

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:16:00

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered '09 Jan 2021'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:47

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:16:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered 'MRI'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:47

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:16:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	02 Mar 2021 14:55:47

US3242107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:16:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:57:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:45:26
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	02 Mar 2021 22:02:47
User entered empty.	Donna Toepfer (b) (4)	02 Mar 2021 14:55:47

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'USA-US067-2021-MRNA-1273-P301000003'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Nathan'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Segall'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:28
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '175 country club dr st100a'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Stockbridge'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:18:04
User closed query 'Please enter State of site address' (Site from CRA).	(b) (4)	19 Apr 2021 13:34:20
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:06
Query 'Please enter State of site address' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:51:39
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 14:51:23
User opened query 'Please enter State of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:43:52

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:35
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '30281'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 18:19:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
User entered 'US'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 14:41:36
User entered '3'	System	16 Feb 2021 14:41:36
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '2'	System	05 Feb 2021 18:20:11
User entered '1'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'USA-US067-2021-MRNA-1273-P301000003'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Nathan'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Segall'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:28
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '175 country club dr st100a'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Stockbridge'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:18:04
User closed query 'Please enter State of site address' (Site from CRA).	(b) (4)	19 Apr 2021 13:34:20
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:06
Query 'Please enter State of site address' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:51:39
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 14:51:23
User opened query 'Please enter State of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:43:52

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:35
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '30281'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 18:19:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
User entered 'US'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 14:41:36
User entered '3'	System	16 Feb 2021 14:41:36
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '2'	System	05 Feb 2021 18:20:11
User entered '1'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:16:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
User entered '13/Jan/2021 23:57'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:16:00

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 18:19:56
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:44:33
User entered 'I'	(b) (4), (b) (6)	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'USA-US067-2021-MRNA-1273-P301000003'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Nathan'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Segall'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:28
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '175 country club dr st100a'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Stockbridge'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:18:04
User closed query 'Please enter State of site address' (Site from CRA).	(b) (4)	19 Apr 2021 13:34:20
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:06
Query 'Please enter State of site address' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:51:39
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 14:51:23
User opened query 'Please enter State of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:43:52

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:35
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '30281'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 18:19:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
User entered 'US'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 14:41:36
User entered '3'	System	16 Feb 2021 14:41:36
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '2'	System	05 Feb 2021 18:20:11
User entered '1'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:16:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '05/Feb/2021 18:20'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:16:00

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)	19 Apr 2021 13:34:06
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'USA-US067-2021-MRNA-1273-P301000003'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'Yes (Y)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 23:57:13
User entered 'No (N)'	System	13 Jan 2021 23:56:12

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Nathan'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Segall'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:28
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '175 country club dr st100a'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered 'Stockbridge'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:18:04
User closed query 'Please enter State of site address' (Site from CRA).	(b) (4)	19 Apr 2021 13:34:20
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:06
Query 'Please enter State of site address' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:51:39
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 14:51:23
User opened query 'Please enter State of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:43:52

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:43:35
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:41:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '30281'	System	05 Feb 2021 18:20:11

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 19:42:50
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 18:19:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:44:33
User entered 'US'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:16:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
	(b) (4)	
Signature has been broken.	System	16 Feb 2021 14:41:36
User entered '3'	System	16 Feb 2021 14:41:36
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 19:42:50
User entered '2'	System	05 Feb 2021 18:20:11
User entered '1'	System	13 Jan 2021 23:57:20

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:16:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
User entered '16/Feb/2021 09:41'	System	16 Feb 2021 14:41:36

US3242107

Folder: SAE USA-US067-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:16:00

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)	19 Apr 2021 13:34:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	17 Feb 2021 17:20:07
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 14:41:36